UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

GREGORY W. BARAN, M.D.,	:	**Case No. 1:04cv1251**
Plaintiff,	:	**JUDGE KATHLEEN O'MALLEY**
v.	:	
MEDICAL DEVICE TECHNOLOGIES, INC., et al.,	:	**MEMORANDUM & ORDER**
Defendants.	:	

In this patent action, Defendant Medical Device Technologies, Inc. ("MDTech") has filed a *Motion for Summary Judgment of Noninfringement* (Doc. 164, "MSJ"). By way of its motion, MDTech argues that there is no genuine issue of material fact that MDTech does not infringe claim 7 of U.S. Patent No. 5,025,797 (the "'797 Patent"). Plaintiff Gregory W. Baran, M.D. ("Baran") opposes the motion, which has been fully briefed and is now ripe for adjudication.[1] For the reasons articulated below, MDTech's motion for summary judgment is **GRANTED** and this case is

[1] MDTech's MSJ was filed on December 22, 2008 (Doc. 164). Baran filed a response in opposition to the motion for summary judgment on January 26, 2009 (Doc. 171), and, with MDTech's consent, filed a corrected brief in opposition on February 12, 2009 (Doc. 179, "Opp'n Br."). MDTech filed a reply in support of its MSJ on February 12, 2009 (Doc. 180, "Reply Br.").

DISMISSED.[2]

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[2] Also ripe and pending before the Court is Baran's motion for leave to file a sur-reply brief (Doc. 181, "Mt. for Leave to File Sur-Reply"), which MDTech opposes (Doc. 182). Both parties acknowledge that a sur-reply is not appropriate under the rules without leave of Court, which may be granted to allow the moving party to address new arguments raised in the reply brief. After full consideration of the parties' briefs, Baran's Mt. for Leave to File Sur-Reply is **DENIED**; the Court will not consider Docs. 181, 182 or 185 in analyzing MDTech's MSJ. The Court disagrees with Baran's claim that the arguments in the Reply Br. are "new." Each was raised and addressed in the MSJ, Opp'n Br., and Reply Br. The central issue Baran wishes to address by way of sur-reply is whether the Court should strike the declaration he personally submitted in support of his Opp'n Br., which includes a report setting forth his infringement opinions, and numerous exhibits thereto. Baran identified this issue in footnote 1 of his Opp'n Br. and argued that it is appropriate for the Court to consider his declaration. MDTech responded with the suggestion that the Court strike the declaration. Therefore, the issue has been framed for the Court's consideration; it is not new. Similarly, the infringement arguments presented in the proposed sur-reply simply expand upon arguments Baran already raised. Although the proposed sur-reply brief might provide a more thorough or refined articulation of Baran's position with respect to the arguments he identifies, the purpose of a sur-reply is not to permit re-argument after additional reflection.

As for Baran's declaration, the Court will only consider those portions of the declaration that are authorized by the Federal Rules of Evidence. *Id.* The vast majority of Baran's declaration is opinion testimony based on "scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701. Although Baran did not identify himself as an expert as required by Rule 26(a)(2) of the Federal Rules of Procedure and the Court's Case Management Plan (Doc. 25), he is attempting to present expert testimony by way of a declaration pursuant to Rule 56(e) of the Federal Rules of Procedure. *See* Fed. R. Civ. P. 26(a)(2) ("[A] party must disclose to the other parties the identity of any witness it may use at trial to present evidence under Federal Rule of Evidence 702, 703, and 705."). Rule 56(e) requires that affidavits (and declarations) submitted in opposition to summary judgment comply with the rules of evidence. His declaration is, as a practical matter, an expert report in which he provides his infringement opinion. Baran's "expert report" was submitted well after the deadline for exchanging expert reports established by the Case Management Plan for this matter (Doc. 25) and without notice to MDTech. Accordingly, to the extent it provides expert testimony, the Court has not considered it in analyzing MDTech's MSJ. Baran cites *Ekstam v. Ekstam*, 2007 WL 2571968 (E.D. Mo. 2007), for the proposition that the Court should excuse his failure to comply with the procedural prerequisites to providing expert testimony. The Court is not persuaded by *Ekstam*. It is not binding authority, and it is readily distinguishable because the *Ekstam* court found that the affidavit at issue substantially satisfied Fed. R. Civ. P. 56(e).

I. BACKGROUND[3]

This is a patent infringement lawsuit relating to a biopsy instrument manufactured, distributed, and sold by MDTech. The allegedly infringing biopsy instrument is known as the BioPince® Full Core Biopsy Instrument ("BioPince"). In his Complaint,[4] Baran alleges that MDTech willfully infringed both U.S. Patent No. 5,400,798 (the "'798 Patent") and the '797 Patent by manufacturing, distributing, and selling the BioPince.

A. PROCEDURAL HISTORY

After briefing and a hearing, the Court issued an Opinion & Order construing the disputed claim limitations of the patents at issue pursuant to *Markman v. Westview Instruments*, 517 U.S. 370 (1996) ("*Markman* Opinion"). Although his Complaint assert generally that MDTech has directly or indirectly infringed one or more claims of the '797 and '798 Patents, Baran narrowed the asserted claims to claim 7 of the '797 patent and claim 2 of the '798 Patent during the claim construction process. Further, after the *Markman* Opinion issued, the parties filed a joint stipulation stating that, in light of the Court's construction of certain limitations in claim 2 of the '798 Patent, Baran "admits that he cannot prove that the . . . BioPince, . . . as made, used, offered for sale, or sold by [MDTech]

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[3] The background of this case (including an account of procedural oddities relating to the participation of additional defendants) is set forth in some detail in the Court's *Markman* Opinion (Doc. 132 at 2-3). The Court expressly incorporates that description into this Opinion & Order. In the interest of judicial efficiency, the Court will not repeat it here, except to the extent necessary to address the motions presently pending.

[4] "Complaint" refers to Dr. Baran's *Second Amended Complaint for Willful Patent Infringement* (Doc. 60).

is an infringement of claim 2 of the '798 patent." (Doc. 145, Jt. Stipulation Re: '798 Patent.)[5] Consequently, the only infringement allegations remaining after the Joint Stipulation are those relating to claim 7 of the '797 Patent.

B. ISSUE

The issue on summary judgment is whether, in view of the Court's construction of the three debated limitations of claim 7 of the '797 Patent, MDTech is entitled to judgment of noninfringement as a matter of law because there is no genuine issue of material fact with respect to infringement as to at least one limitation of the claim.

C. BACKGROUND OF THE INVENTION: THE '797 PATENT & THE BIOPINCE

A basic understanding of the patent and allegedly infringing device – the BioPince – is necessary to understand and address this issue.

1. Biopsy Instruments & the '797 Patent

In the *Markman* Opinion, the Court described biopsy instruments generally, and the '797 Patent specifically, in the "Overview of the Invention" section. In pertinent part, that section is set forth below.[6]

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[5] The Joint Stipulation also states that Baran objects to the Court's construction of claim 2 of the '798 Patent, and notes that both parties reserve the right to appeal the Court's *Markman* Opinion.

[6] The footnotes in the quoted section of the *Markman* Opinion appear as footnotes 6-8 of this Opinion & Order. To identify these footnotes as quotations, they are indented.

A. Overview of the Invention[7]

As mentioned at the outset, Baran's patents are directed at an automated biopsy instrument. To give context to Baran's invention and the problems it was intended to remedy, the Court first reviews biopsy instruments in general before addressing Baran's specific invention.[8]

A biopsy instrument, generally, is a device for removing a sample of tissue from a human being or animal for diagnosis. Prior to the advent of biopsy instruments, tissue specimens primarily were obtained through invasive exploratory surgery. Biopsy instruments enabled medical professionals to obtain tissue samples with less risk of trauma and damage to a patient. Most contemporary biopsy instruments remove the tissue sample through the use of a two part needle set comprised of a stylet, which is a slender probe or wire, and a cannula, which is a hollow tube that surrounds the stylet and can be inserted into the body. The cannula, and sometimes the stylet, are sharp or pointed so that they are capable of cutting through or piercing tissue.

There are two primary methods of obtaining a tissue specimen that the parties described in their briefs and at the *Markman* hearing. Each method involves the use of a different type of needle. . . .

The . . . method [used in the BioPince] involves a full-core needle, which, as the name implies, employs a stylet that does not contain a slot or gap. With this method, the cannula extends beyond the stylet and is inserted into the tissue. The tissue sample fills the hollow portion of the cannula. Once the needle is withdrawn from the patient, the stylet can then be advanced into the cannula to eject the sample from the cannula. Typically, this method requires some sort of negative pressure or suction to ensure that the specimen actually stays inside the cannula when it is withdrawn. Counsel for MDTech analogized this method to putting a straw in a cola

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[7] The claims at issue in this case, although from two different patents, refer to the same invention. The '798 patent is a later filed Continuation-in-Part of the '797 patent, but the new matter introduced in the '798 patent is not at issue here. The portions of the '797 specification and '798 specification relevant to the Court's analysis, therefore, are nearly identical. To avoid redundancy, the Court cites only to the '797 specification in providing a general overview of the invention.

[8] The following information was gleaned by the Court from the parties' briefs, the parties' oral arguments, the prior art disclosed in the patents at issue, and the patents themselves.

bottle - a user needs to put his finger over the straw when it is removed in order to capture some cola in the straw. (Transcript from *Markman* Hearing (hereinafter, "Tr."), at 76.)

. . .

In different biopsy instruments, movement of the stylet and cannula can be manual, semi-automated, or automated. A manually operated biopsy device, of course, requires the user to move the cannula and the stylet by hand. The semi-automated and automated biopsy instruments, however, contain some sort of part or mechanism to move either the cannula, the stylet, or both. . . . The benefits of the semi-automated and automated devices over the manual devices are that the cutting motion is swifter, which causes a cleaner cut, does less damage to the surrounding tissue, and shortens the length of the procedure; the automated devices are more accurate; and there is less risk of inherent human error in operating the cannula and stylet.

With that background, the Court now turns to the patents at issue in this case. The '797 patent was filed on March 29, 1989 and issued on June 25, 1991 . . . . As the prior art above shows, the invention disclosed in these patents was not the first for an automated biopsy instrument; it was an improvement on existing automated instruments. In the Background of the Invention, the patent identifies certain problems with instruments known at the time, primarily related to the ease of use and risk of accident. Specifically, the patent explains that "the various automated biopsy instruments presently known tend to be heavy, difficult to manipulate, and incorporate biasing mechanisms[9] which are either complicated in construction or require undue force to operate." ('797 patent, col. 3, l. 8-12.) In addition, the Background of the Invention identifies the possibility of "inadvertent movement or torque," especially in the case of instruments that permit or require elements to be manually adjusted prior to advancement of the cannula. (*Id.*, col. 3, l. 14-20). Likewise, some instruments contain a moveable stylet that extends beyond the rear of the instrument, leaving it vulnerable to accidental impact and inadvertent advancement into the body. (*Id.*, col. 2, l. 37-47.) Finally, the Background of the Invention notes that the known instruments have exposed triggers or releases that actuate the movement of the cannula or stylet, thus further creating the risk of accidental advancement of the cannula. (*Id.*)

To address those perceived problems, the '797 patent provides an instrument with a stationary stylet that, once mounted to the instrument, cannot be moved

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[9] Biasing mechanisms are the mechanisms that charge and discharge the cannula and the stylet for advancement into the tissue. The parties agree on the meaning of this phrase.

inadvertently or otherwise. (*Id.*, col. 3, l. 30-35.) It also describes a guide on which a cannula can be mounted that can be manually moved to the charged position against the urging of a biasing mechanism such as a coil spring, and can be released to the discharged position, advancing in the direction of the stylet by a manually actuable release means. (*Id.*, col. 2, l. 35-44.) To address the problem of an exposed trigger or release, the patent describes that, "[i]n the preferred embodiments of the invention, a shield means is provided which is disposed to block or prevent inadvertent actuation of the release means." (*Id.*, col. 2, l. 58-60.) . . .

There are two basic embodiments in the '797 and '798 patents. One embodiment, depicted in Fig. 1 of both patents, relates to a reusable configuration that permits needle sets to be used and replaced, so that the instrument can be used multiple times for multiple patients. The second embodiment, depicted in Fig. 5 of both patents, relates to a single use configuration that can be used on only one patient. An exploded view of the first embodiment, taken from Fig. 1, is shown [below]:

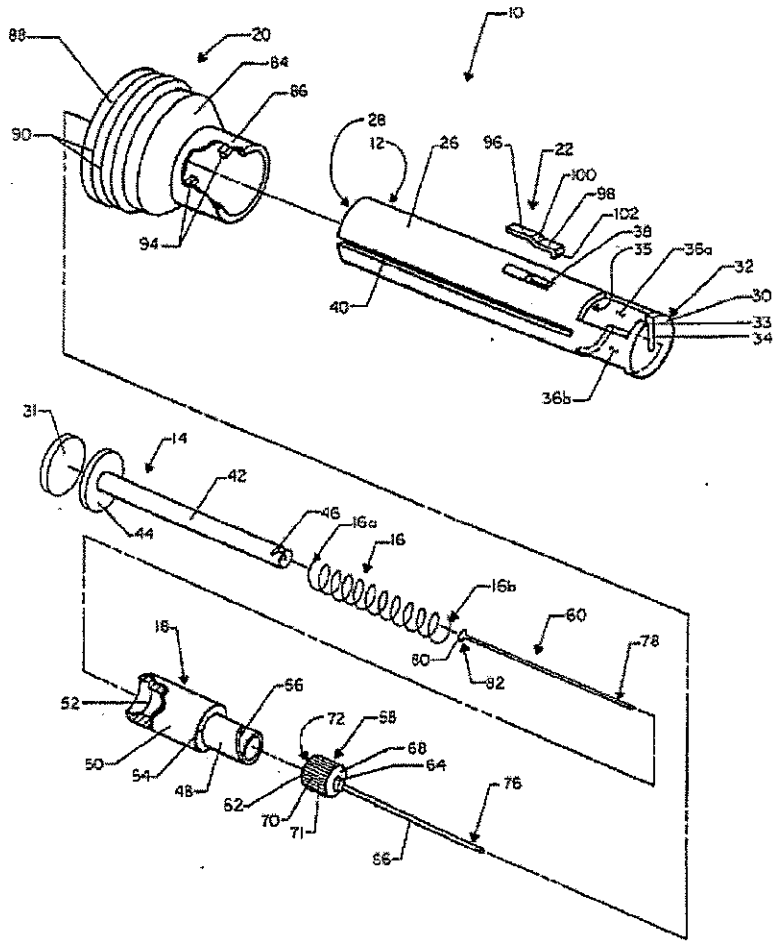
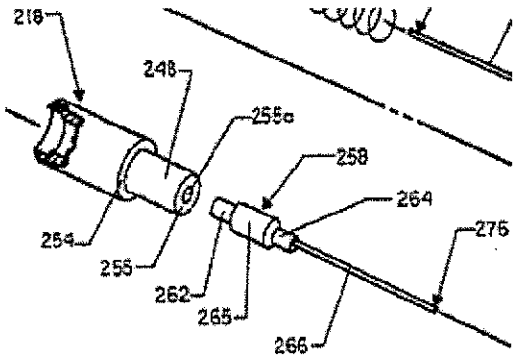


FIG. 1

The automated instrument **10** as shown in Fig. 1 includes the following primary components: an outer casing **12**; a support rod **14**; a coil spring **16**; a biopsy spring guide **18**; a safety cap **20**; a release lever **22**; and a needle **24**. ('797 patent, col. 4, l. 47-51.) A needle **24** is not shown in this illustration (it is shown in Figure 1A), but it comprises a stylet **60** and a cannula mount **58**, which, in turn, comprises a cylindrical collar **62**, a conical head **64**, and a cutting cannula **66**. (*Id.*, col. 4, l. 37-40.) . . .

According to the Detailed Description of the Invention, the instrument is converted from the discharged mode to the charged-safety-on mode (meaning it is ready to fire, but there is a shield over the release) by retracting the safety cap **20** toward the rear end **28** of the tube **26**. (*Id.*, col. 7, l. 4-7.) This action causes the guide pins **94** to engage the annular external shoulder **54** of the spring guide **18** to retract the spring guide toward the base **44** of the support rod **14** and compress the coil spring **16**. (*Id.*, col. 7, l. 12-16.) In other words, according to that description, the charge is created when the safety cap is pulled backward and the guide pins on the inside of the safety cap structure catch the shoulder of the spring guide, which compresses the spring back toward the base. This action creates the charge that, once the release is pressed, causes the cannula to advance forward over the stylet.

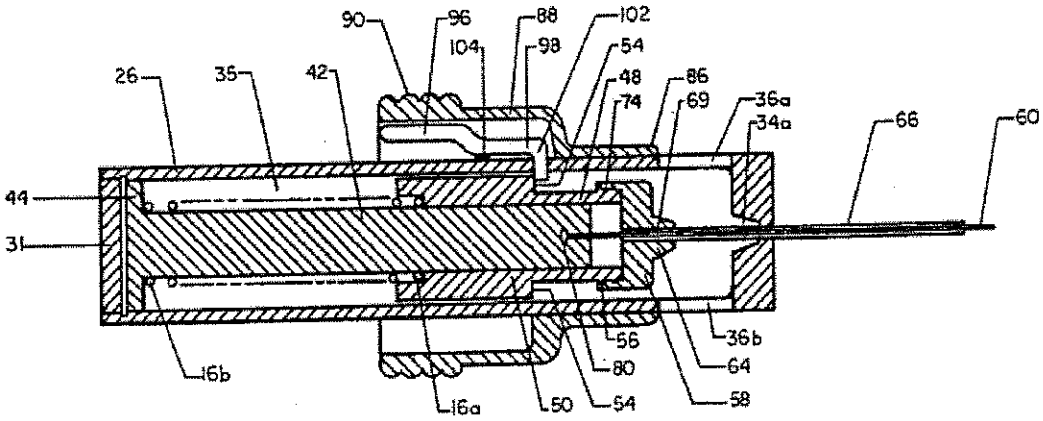
As between Fig. 1 (the reusable embodiment) and Fig. 5 (the single use embodiment), the most significant difference for purposes of the Court's present analysis is the cannula mount, specifically the cannula mount's interaction with the spring guide. The relevant portion of Fig. 5 is shown to the right. As depicted, rather than have a screw-on feature like the cannula mount in Fig. 1, this embodiment has a plug-in type feature, where the cannula mount **258** receives the cannula **266** on one end and plugs into the guide **218** by inserting the base **262** into a bore **255*a*** in the guide.



These descriptions of the invention are meant to provide some background to the claims at issue in this case. The remaining elements of the invention will be discussed below, where applicable . . . .

(*Markman* Opinion at 9-16.) The figure below from the front page of the patent provides an

overview of one embodiment of the '797 Patent in its charged-ready mode.



2. The BioPince

The BioPince is an automated biopsy instrument that uses a full-core needle. The figures below, Figure 1 from Baran's Opp'n Br. and Figure 1 from MDTech's MSJ, depicts one of the allegedly infringing models of the BioPince.[10]

BELOW: Fig. 1, Opp'n Br. at 3; Fig. 1, MSJ at 4.

[10] Baran identifies two allegedly infringing models of the BioPince: Model No. 360-1080-01, which has a green cocking arm, and a later redesigned model with a blue cocking arm. (Opp'n Br. at 3.) The parties agree that these two models – the "green" and "blue" models – are identical for purposes of this Court's infringement analysis.

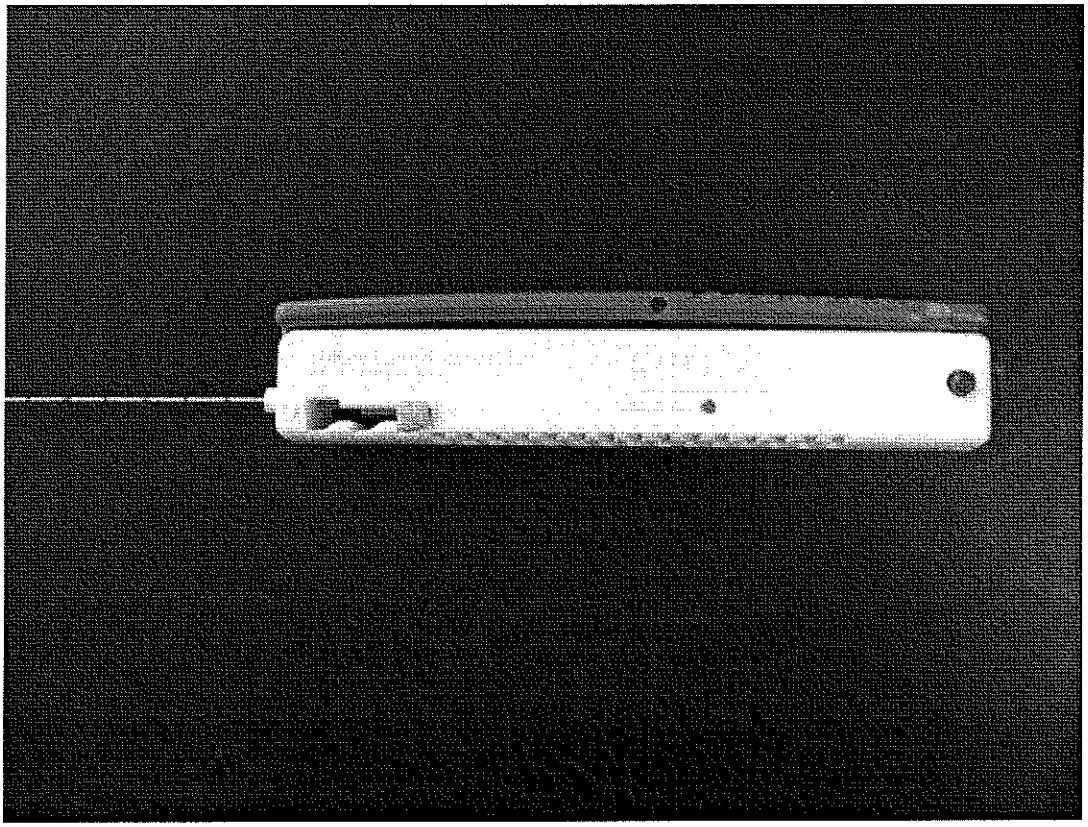


Figure 1 – Opp'n Br.

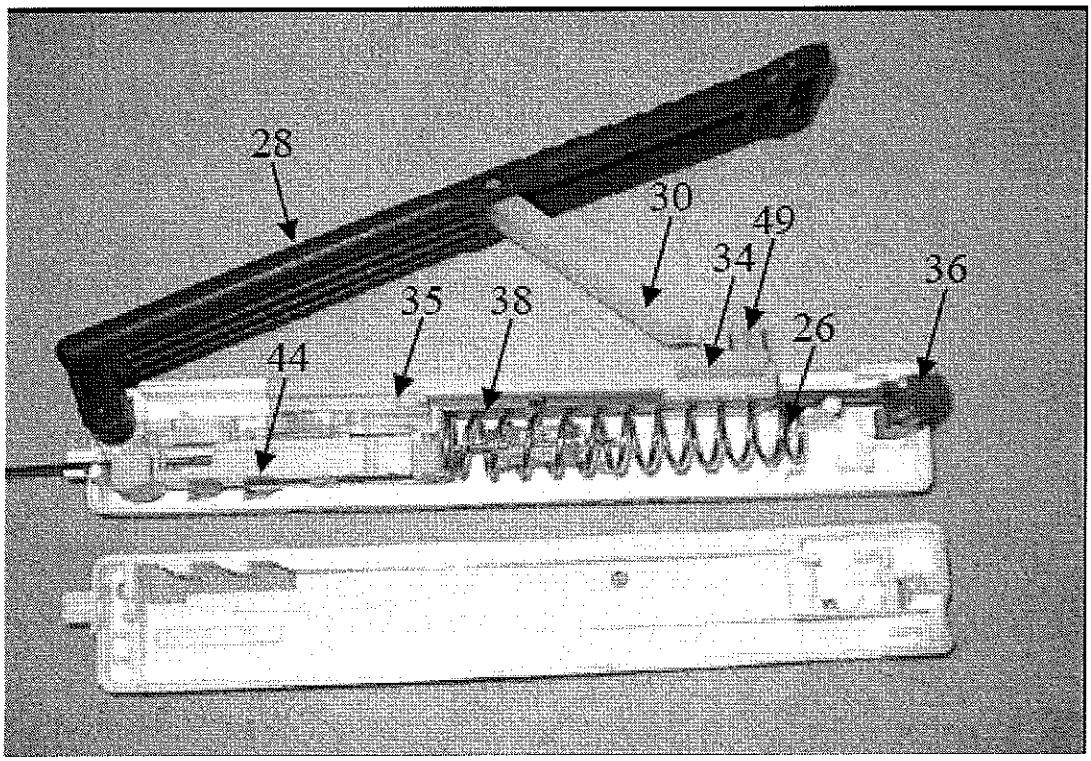
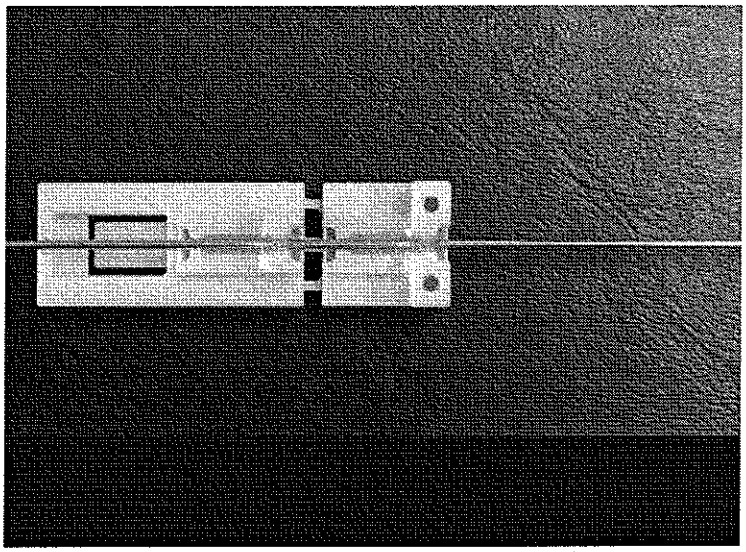


Figure 1 – MSJ

As illustrated by the figures above, the BioPince includes a white plastic casing housing the internal components of the device, and a needle, protruding from the casing on the left side of the figure. The needle consists of three components: (1) a solid stylet sharpened to a point at its distal end, inside (2) a hollow inner cannula (also referred to as a cutting cannula because the circumference of its distal end is sharpened for cutting through tissue), both of which are inside (3) a hollow outer tube. The stylet extends beyond the hollow outer tube and cannula in the direction opposite the distal end of the needle, and is attached to a plastic retaining block. The stylet extends through the center of the spring **26**. The cannula and the outer tube are attached to interlocking guides by a patch of adhesive; the outer tube is glued to the front guide while the cannula is glued to the back guide.



The interlocking guides are connected such that they move together as the BioPince is placed into

a charged[11] position and during the first part of the spring-propelled discharge.

The BioPince includes a crank arm **28** pivotally connected to the end of the casing directly above the point at which the needle protrudes from the casing. Along with several other components, including, but not limited to, the connecting rod **30**, crank arm fixer **34**, and slider link **35**, the crank arm forms a mechanism[12] for charging the spring **26**.

To charge the spring, the user holds the casing in one hand and lifts the crank arm away from the casing with the other until the locking groove in the slider link engages with the latching protrusion on the front guide. The sound of a "click" indicates that the locking groove has engaged with the latching protrusion. Then, the user pushes the crank arm toward the casing, thus compressing the spring between the back guide and the end of the housing containing the trigger button **36**. The BioPince is charged when a second click indicates that the crank arm locking tab positioned on top of the crank arm fixer inserts through the slot in the crank arm and engages the shoulder of the slot, thereby locking the crank arm to the crank arm fixer. The BioPince can now be fired by moving the safety to the "fire" position and pressing the trigger button **36**.

Pressing the trigger button pushes the distal end of the elongated release bar **38** toward the latching protrusion of the front guide. The distal end of the elongated release bar acts as an inclined plane inserted between the latching protrusion and slider link to release the cannula guides. Thus, pressing the trigger button releases the elastic potential energy from the compressed spring and

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[11] Both parties describe the BioPince as "charged" when the spring is compressed such that, when released, its elastic potential energy propels the guides in the direction of the distal end of the stylet to take a biopsy sample.

[12] This mechanism will be referred to as the "slider-crank mechanism" in this Memorandum & Order.

propels the guides and cannula in the direction of the distal end of the needle, into the tissue to be sampled.

To retrieve the sample, the user completely removes the BioPince needle from the subject and charges the device again, causing the stylet to advance through the cannula and expel the tissue sample retained therein. This leaves the BioPince in the charged position, ready to take another tissue sample from the same subject. Therefore, the BioPince will ultimately be in the charged position after all biopsy samples have been retrieved.

D. THE COURT'S CONSTRUCTION OF THE LIMITATIONS OF CLAIM 7

In its *Markman* Opinion, the Court construed several limitations of claim 7 of the '797 Patent. Claim 7 of the '797 Patent provides as follows, with the terms the Court construed in bold.

> 7. A biopsy instrument comprising an elongate hollow casing, a needle extending outwardly from the casing and having a cannula and a stylet received within the cannula, a stationary support mounted within the casing in fixed relation thereto and having means affixing the stylet thereto, a cannula guide, **a cannula mount affixing the cannula to the guide**, the guide being completely enclosed by the casing for reciprocating movement therewithin relative to the stationary support between a charged position, wherein the cannula is retracted in a direction away from the distal end of the stylet, and a discharged position, wherein the cannula is displaced from the charged position in the direction of the distal end of the stylet, a coil spring engaged between the stationary support and the guide for urging the guide toward the discharged position, **a manually operable charging member for moving the guide to the charged position against the urging of the coil spring,** and **a release means for retaining the guide in the charged position**.

('797 patent, col. 12, l. 54 - col. 13, l.5.) The Court construed the disputed terms in claim 7 of the '797 patent as follows:

TERM	CONSTRUCTION
a cannula mount affixing the cannula to the guide	a structure or support which attaches or connects the cannula to the guide
a manually operable charging member for moving the guide to the charged position against the urging of the coil spring	a manually operable charging member that is used to create a charge or stored energy, the charging member configured to move the guide to the charged position against the urging of the coil spring
a release means for retaining the guide in the charged position	Means-plus-function claim in which the function is "retaining the guide in the charged position and releasing, or setting free, the guide from the charged position." The structures corresponding to this function are: (1) for the reusable embodiment (Figs. 1 - 4A), the release lever **22**, including the latching projection **102**, the finger rest **96**, mounting section **98**, and connecting web **100**, as well as the equivalents thereof; and (2) for the single use embodiment (Figs. 5-8A), the release lever **222**, including the latching projection **302** and the mounting section **298**, as well as the equivalents thereof

(*Markman* Opinion at 49-50.) Each of these claims is at issue on summary judgment and will be discussed further below.

II. DISCUSSION

A. THE LEGAL STANDARD FOR A MOTION FOR SUMMARY JUDGMENT

MDTech has moved for summary judgment of noninfringement under Rule 56 of the Federal Rules of Civil Procedure. (Doc. 164.) Under Rule 56(c), summary judgment should be granted "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law."

Fed. R. Civ. P. 56(c); *see also Vita-Mix Corp. v. Basic Holding, Inc.*, — F.3d —, 2009 WL 2950226, *3 (Fed. Cir. Sept. 16, 2009). This standard applies in patent cases just as it does in other areas of law. *Nike, Inc. v. Wolverine World Wide, Inc.*, 43 F.3d 644, 646 (Fed. Cir. 1994). .

In reviewing summary judgment motions, this Court must view evidence in the light most favorable to the non-moving party to determine whether a genuine issue of material fact exists. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144 (1970); *Ball Aerosol & Specialty Container, Inc. v. Limited Brands, Inc.*, 555 F.3d 984, 991 (Fed. Cir. 2009); *CenTra, Inc. v. Estrin*, 538 F.3d 402, 412 (6th Cir. 2008); *Ricoh Co., Ltd. v. Quanta Computer, Inc.*, 550 F.3d 1325, 1330 (Fed. Cir. 2008). A fact is "material" only if its resolution will affect the outcome of the lawsuit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Daugherty v. Sajar Plastics, Inc.*, 544 F.3d 696, 702 (6th Cir. 2008). Determination of whether a factual issue is "genuine" requires consideration of the applicable evidentiary standards. Thus, in most civil cases, the Court will decide "whether reasonable jurors could find by a preponderance of the evidence that the [non-moving party] is entitled to a verdict." *Anderson*, 398 U.S. at 252.

Upon filing a motion for summary judgment, the moving party has the initial burden of establishing that there are no genuine issues of material fact as to an essential element of the non-moving party's claim. *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479-80 & n.12 (6th Cir. 1989); *Moldowan v. City of Warren*, 570 F.3d 698, 719 (6th Cir. 2009). The moving party, however, is not required to file affidavits or other similar materials negating a claim on which its opponent bears the burden of proof, so long as the moving party relies upon the absence of the essential element in the pleadings, depositions, answers to interrogatories, and admissions on file. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Curto v. Harper Woods*, 954 F.2d 1237, 1241 (6th Cir. 1992)

(quoting *Ceolotex*, 477 U.S. at 322); *Ocean Innovations, Inc. v. Quarterberth, Inc.*, No. 1:03-CV-0913, 2009 U.S. Dist. LEXIS 54108, at *8-9 (N.D. Ohio June 26, 2009) (citing *Ceolotex*, 477 U.S. at 322).

In response, if the moving party establishes the absence of a genuine issue of material fact, to defeat summary judgment, the non-moving party "may not rely merely on allegations or denials in its own pleading; rather, its response must – by affidavits or as otherwise provided in this rule – set out specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e)(2); *see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986). In this regard, "Rule 56 does not impose upon the district court a duty to sift through the record in search of evidence to support a party's opposition to summary judgment"; rather, "Rule 56 allocates that duty to the opponent of the motion, who is required to point out the evidence, albeit evidence that is already in the record, that creates an issue of fact." *Williamson v. Aetna Life Ins. Co.*, 481 F.3d 369, 379-80 (6th Cir. 2007) (citation omitted). Moreover, the non-moving party must show more than a scintilla of evidence to overcome summary judgment; it is not enough for the non-moving party to show that there is some metaphysical doubt as to material facts. *Matsushita Elec. Indus. Co.*, 475 U.S. at 586-87; *see also Vita-Mix*, — F.3d —, 2009 WL 2950226 at *3; *Barr v. Lafon*, 538 F.3d 554, 574 (6th Cir. 2008).

Accordingly, the ultimate inquiry is whether the record, as a whole, and upon viewing it in the light most favorable to the non-moving party, could lead a rational trier of fact to find in favor of the non-moving party. *Matsushita Elec. Indus. Co.*, 475 U.S. at 586-87; *see also Anderson*, 477 U.S. at 252 ("The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the [non-moving party] is entitled to a verdict – whether

there is [evidence] upon which a jury can properly proceed to find a verdict for the party producing it, upon whom the onus of proof is imposed.") (emphasis in original) (internal quotations omitted); *Amgen, Inc. v. F. Hoffman -LA Roche Ltd.*, — F.3d —, 2009 WL 2928763, *7 (Fed. Cir. Sept. 15, 2009).

In the context of a patent infringement case, "whether a particular device infringes a properly construed claim[] is a question of fact." *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 (Fed. Cir. 1998). Consequently, summary judgment of noninfringement only is appropriate where "no reasonable fact finder could find infringement." *Id.* As stated by the Federal Circuit: "We affirm a district court's grant of summary judgment of non-infringement only if, after viewing the alleged facts in the light most favorable to the non-movant, there is no genuine issue as to whether the accused device is encompassed by the claims." *Wavetronix LLC v. EIS Electronic Integrated Sys.*, 573 F.3d 1343, 1354 (Fed. Cir. 2009) (quoting *Combined Sys., Inc. v. Def. Tech. Corp. of Am.*, 350 F.3d 1207, 1210 (Fed.Cir.2003) (citation omitted)).

B. STANDARDS FOR PATENT INFRINGEMENT

"Infringement analysis involves a two-step process: the court first determines the meaning of disputed claim terms and then compares the accused device to the claims as construed." *Wavetronix LLC*, 573 F.3d at 1354 (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995), *aff'd*, 517 U.S. 370 (1996); *see also Middleton, Inc. v. Minn. Mining & Mfg. Co.*, 311 F.3d 1384, 1387 (Fed.Cir.2002)).

Claim construction is a matter of law. *Markman*, 52 F.3d at 976. In this case, the Court has already construed the limitations of the claim at issue in an extensive *Markman* Opinion. Therefore, the first step of the infringement analysis is theoretically complete. The existence of the *Markman*

Opinion does not preclude the Court from re-visiting its constructions as its understanding of the technology at issue is informed by the infringement analysis, however. *See Jang v. Boston Scientific Corp.*, 532 F.3d 1330, 1337 (Fed. Cir. 2008) ("Indeed, a better understanding of the context of the claim construction as a case proceeds through an infringement determination can appropriately lead a district court to change its initial claim construction."); *Kendall Mfg. Co. v. Genlyte Thomas Group LLC*, 439 F. Supp. 2d 854, 862 (N.D. Ill. 2006) (choosing to "clarify and elaborate on" initial claim construction "so as to eliminate further confusion-or manipulation-of its meaning by the parties.").

The second step in the infringement analysis – comparison of the claims to the accused device – is a question of fact. *Ethicon Endo-Surgery, Inc.*, 149 F.3d at 1315. The "all elements rule" applies to the process of comparing the claims to the accused device: "an accused product or process is not infringing unless it contains each limitation of the claim, either literally or by an equivalent." *PSN Illinois, LLC v. Ivoclar Vivadent, Inc.*, 525 F.3d 1159, 1168 (Fed. Cir. 2008) (quoting *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1358 (Fed.Cir.2005)).

In general, a patent may be infringed literally or under the doctrine of equivalents. Literal infringement occurs when each limitation or element of a claim of the patent at issue is present in the accused device. *Id.*; *see also Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996). Even if each limitation or element of a claim is not literally met by the accused device, infringement may be found under the doctrine of equivalents if the differences are insubstantial. *See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1351 (Fed. Cir. 2003). "Infringement analysis under the doctrine of equivalents proceeds element-by-element; a generalized showing of equivalency between the claim as a whole and the allegedly infringing product or process is not sufficient to show infringement." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1296 (Fed. Cir.

2009) (citing *Warner-Jenkinson Co. v. Hilton-Davis Chemical Co.*, 520 U.S. 17, 29 (1997), stating that "the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole"); *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1305 (Fed. Cir. 2007) (citing *Texas Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996)) ("[G]eneralized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice.").

One way to determine whether each element in the patent has an equivalent in the accused device is to analyze whether the element in the accused device "performs substantially the same function in substantially the same way to obtain the same result" as the corresponding claim limitation in the patent. *Abbott Labs.*, 566 F.3d at 1296. This is known as the "function-way-result" or "triple identity" test. *Id.* To prove infringement under the function-way-result test, the plaintiff must produce "*evidence* to establish *what* the function, way, result of *both* the claimed device and the accused device are, and *why* those functions, ways and results are substantially the same[.]" *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1327 n.5 (Fed. Cir. 1991) (emphasis in original).

The function-way-result test is not the only method of proving infringement under the doctrine of equivalents, however, because "[d]ifferent linguistic frameworks may be more suitable to different cases[.]" *Warner-Jenkinson*, 520 U.S. at 40. "Equivalency may also be proven where the differences between the invention as claimed and the accused product or process are insubstantial." *Abbott Labs.*, 566 F.3d at 1297 (citing *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1517-18 (Fed.Cir.1995) (*en banc*), *rev'd* on other grounds, 520 U.S. 17 (1997)). This is known as the insubstantial differences test. *Id.*

C. ANALYSIS OF THE DISPUTED ASPECTS OF CLAIM 7

Baran contends that the BioPince contains each of the three limitations of claim 7 of the '797 Patent that the Court construed in its *Markman* Opinion. MDTech moves for summary judgment of noninfringement on the grounds that the BioPince does not contain any of these limitations as a matter of law. The Court will now address each of the disputed limitations in turn.

1. The Cannula Mount Limitation: "a cannula mount affixing the cannula to the guide"

The first disputed term of claim 7 of the '797 Patent is "a cannula mount affixing the cannula to the guide."

a. The Court's Construction of the Cannula Mount Limitation

The Court construed "a cannula mount affixing the cannula to the guide" as "a structure or support which attaches or connects the cannula to the guide." (*Markman* Opinion at 49-50.) In so holding, the Court rejected Baran's argument that the "cannula mount" can be "anything." Specifically, the Court explained as follows:

> The Court agrees with MDTech that, based on the specification, prosecution history, and dictionary definition, "cannula mount" cannot simply mean "anything." Rather, the Court concludes that this language contemplates and, thus, claims a piece or structure which is independent from the structures which are the guide and the cannula, and serves the function of connecting the two other structures. Thus, the Court construes "a cannula mount affixing the cannula to the guide" to mean "a structure or support which attaches or connects the cannula to the guide."

(*Markman* Opinion at 19-20.)

The Court notes several additional aspects of its construction of this limitation worthy of consideration for purposes of resolving this motion for summary judgment. First, the Court noted in the *Markman* Opinion that MDTech's counsel agreed at the *Markman* hearing that the word

"support" could be substituted for the word "structure" in its proposed construction ("a support which attaches the cutting cannula to the guide in a secured manner"). (*Markman* Opinion at 17.) Second, the issue of whether a dab of adhesive alone satisfies this limitation was foreshadowed by the arguments at the *Markman* stage. In opposing Baran's proposed construction that the cannula mount could be "anything" that joins the cannula and the guide together, MDTech specifically noted that "'anything' could include glue, velcro, or other materials that can attach or affix components and that are not themselves structures." (*Id.* at 18.) Third, in spite of the fact that the issue of whether adhesive is a cannula mount was at least presaged at the *Markman* hearing, MDTech did not request, nor did the Court adopt, a negative construction that would unequivocally preclude adhesive from satisfying the cannula mount limitation. Fourth, the Court noted in the *Markman* Opinion that the cannula mount limitation of claim 7 of the '797 Patent was amended from "a guide having means affixing the cannula thereto" to its present form ("a cannula mount affixing the cannula to the guide"). (*Id.* at 19.) In the absence of an alternative explanation for this amendment, the Court concluded that the prosecution history favored a construction requiring an independent entity – *i.e.*, a "structure or support" – as the cannula mount. Finally, although the Court agreed with MDTech that a cannula mount cannot be "anything" that joins the cannula and the guide together, and required a "structure or support" "independent from the structures which are the cannula and the guide," it did not impose the condition that the "independent" cannula mount be "pre-formed."

b. Infringement Analysis

The parties agree that the "cannula mount" in the BioPince consists entirely and exclusively of a dab of "adhesive," and, more specifically, "epoxy." It is undisputed, moreover, that the epoxy used in the BioPince affixes the cannula to the guide. For purposes of summary judgment, the

debate is whether that epoxy is an independent "structure or support" such that it reads on the "cannula mount" limitation of the '797 Patent, either literally or under the doctrine of equivalents. Specifically, the issue is whether the epoxy that affixes the cannula to the guide is a structure or support independent from the structures which are the cannula and the guide. In other words, would substituting "epoxy" for "cannula mount" change the meaning of this particular limitation of claim 7 of the '797 Patent? Based on the parties' submissions, the Court finds that MDTech is not entitled to summary judgment on this issue because there is a material issue of fact with respect to whether the dab of epoxy is, in and of itself, a "support or structure" independent from the structures which are the cannula and the guide.

MDTech argues that the BioPince does not have a "cannula mount" because adhesive, in and of itself, cannot be considered a "structure" or "support." To support its argument, MDTech quotes the Court's conclusion that this limitation of the '797 Patent "contemplates, and, thus, claims a piece or structure which is independent from the structures which are the guide and the cannula, and serves the function of connecting the two other structures" (*Markman* Opinion at 19). MDTech argues that "adhesive has no independent form, uniform geometry, shape, surface area, coverage, or strength as the adhesive will simply flow over the V-shaped trough where the Cannula rests . . . [i]t cannot be independently fabricated." (Opp'n Br. at 26.) MDTech further argues that the teachings of the '797 Patent preclude interpreting the "cannula mount" as a dab of adhesive because the specifications of the patent teach a cannula mount that "can be adhesively bonded to a bore of the guide . . . ." (*Id.* at 27.) Consequently, MDTech contends that, if the cannula mount may be entirely made of adhesive, then the '797 Patent teaches adhesive bonded to adhesive. (*Id.*) In sum, MDTech contends that the specifications of the '797 Patent teach a pre-formed, independent structure playing the role

of the cannula mount while, in the BioPince, adhesive affixes the cannula to the guide and there is no pre-formed, independent "structure" to satisfy the "cannula guide" limitation as construed by the Court.

In addition, MDTech's expert, Dr. Rashidi, testified that a dab of epoxy could never be an independent structure or support because it is merely an agent that "bonds" or "welds" the stainless steel cannula and the plastic guide together. (*See* MSJ at 26.) In other words, Rashidi asserts that the BioPince "simply does not have [a cannula mount], but instead relies on a physiochemical reaction to bond or weld the cannula to the Guide." (*Id.* at 28.) He states that:

> the adhesive connects the cannula to the rear guide with a mechanism of adhesion and adhesion has a very well defined definition. And as I said, there is a physiochemical reaction and interaction among three items, one is solid A, which is the plastic [guide], solid B, which is the stainless steel [cannula], and adhesive agent and the way the adhesion works is creates two boundaries, one is between adhesive and solid A and between adhesive and solid B and they put it all together and that mechanism is very different than having a support structure to connect two pieces together.

(Rashidi Dep. at 160.) Rashidi's fundamental conclusion is that the epoxy cannot be a "structure or support" because it is a bonding agent without an independent structure unto itself.

In response to MDTech's arguments concerning this term, Baran first notes that MDTech argued at the *Markman* hearing that the adhesive connecting the cannula to the guide is not a "structure," but did not argue that the adhesive is not a "support." Accordingly, Baran's first argument is that, since the Court defined a "cannula mount" as a "structure *or support*," and MDTech does not dispute that the adhesive in the BioPince acts as a *support*, there is literal infringement. Further, Baran argues that, although the Court stated that the "cannula mount" is a "piece or structure . . . independent from . . . the guide or cannula," the Court did not impose the

limitations MDTech raises, *i.e.*, "independent form, uniform geometry, shape, surface area, coverage, or strength." In fact, notes Baran, MDTech did not propose such requirements in its proposed constructions at the *Markman* stage, despite the fact that, at the time, MDTech knew Baran considered the adhesive to be the cannula mount.

In sum, Baran argues that whether the adhesive is a structure or a support is a material issue of fact. He asserts that, for example, certain adhesives – such as the epoxy used in the BioPince[13] -- are polymer structures in their hardened form. Accordingly, he argues that whether epoxy in its hardened state is a "structure" or "support" for purposes of the '797 Patent is a jury question.

In response to MDTech expert, Dr. Rashidi, Baran notes that the American Heritage Dictionary defines "epoxy" as "any of various usually thermosetting resins capable of forming tight cross-linked polymer structures characterized by toughness, strong adhesion, and low shrinkage, used especially in surface coatings and adhesives." (Opp'n Br. at 20 (emphasis added).) Baran's expert, Dr. Hagga, similarly testified that a hardened polymer such as epoxy is a structure. (*Id.*) He noted that the determinative factor with respect to whether something is a "structure" should not be its initial state of matter (*i.e.*, solid, liquid, or gas) because, if that were the case, the injection molded plastic used to fabricate, *e.g.*, the guide, would not be a "structure." (Doc. 172-7, Haaga Dep. at 122.)

This evidence indicates that the parties, ultimately, do not dispute that the dab of epoxy has a physical presence and plays a role in establishing the connection between the cannula and the guide. It does not resolve the question of whether the epoxy is a structure or support independent

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[13] It is undisputed that the type of adhesive used in the BioPince to affix the cannula to the guide is an epoxy. (*See* Opp'n Br. at 20.)

of the cannula and guide, however.

The Court finds that Baran has raised a genuine issue of material fact with respect to whether the dab of hardened adhesive that connects the cannula to the guide is the "cannula mount" as the term was construed by the Court. MDTech's description of a dab of adhesive as an amorphous substance whose ultimate physical characteristics depend entirely upon its surroundings is compelling. In addition, MDTech's argument that the specifications do not contemplate a structure consisting of adhesive attached to adhesive is persuasive. But Baran's position has merit as well. Epoxy, like plastic, begins as a liquid but becomes a solid. It performs its function in its solid state. It forms a solid (admittedly, via the principles of adhesion Rashidi alludes to) that surrounds the cannula and the guide, affixing them to it, and, consequently, to each other. Characterizing this solid dab of epoxy as a "structure or support" is not entirely unreasonable. Furthermore, characterized as such, the concept of adhesive attached to adhesive is not so far-fetched. Accordingly, although this is a close question, especially given that, considered in their entirety, the specifications do not appear to contemplate Baran's interpretation, the Court cannot conclude that no reasonable juror could find that the dab of epoxy is "a structure or support which attaches or connects the cannula to the guide." (*Markman* Opinion at 49-50.) Summary judgment of noninfringement is, thus, not appropriate with

respect to this limitation of claim 7.[14]

2. The Charging Member Limitation: "a manually operable charging member for moving the guide to the charged position against the urging of the coil spring"

The second disputed term of claim 7 of the '797 Patent is "a manually operable charging member for moving the guide to the charged position against the urging of the coil spring."

a. The Court's Construction of the Charging Member Limitation

The Court construed "a manually operable charging member for moving the guide to the charged position against the urging of the coil spring" as "a manually operable charging member that is used to create a charge or stored energy, the charging member configured to move the guide to the charged position against the urging of the coil spring." (*Markman* Opinion at 59-60.) In so construing this limitation, the Court specifically chose not to adopt Baran's proposed construction in which a "mechanism" would be synonymous with a "member." (*Id.* at 22.) Instead, the Court found that "the term 'mechanism' is inconsistent with the common and ordinary meaning of 'member' to someone skilled in the art, as well as with what is disclosed in the patent specification." (*Id.*) The Court described the ordinary meaning of the terms "mechanism" and "member" as

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[14] The Court notes that it could conceivably grant summary judgment of noninfringement by adding a negative limitation to its construction of the cannula mount claim – *i.e.*, by finding that a cannula mount cannot be a dab of adhesive based on the fact that, when the specifications mention adhesive, it is in a manner inconsistent with Baran's argument in support of that conclusion. *See, e.g., Kendall Mfg. Co.*, 439 F. Supp. 2d at 862 (choosing to "clarify and elaborate on" initial claim construction "so as to eliminate further confusion-or manipulation-of its meaning by the parties.") The Court concludes that this approach is not appropriate with respect to this claim, however, in light of the fact that (1) MDTech did not request such a construction at the *Markman* stage or in the context of this motion for summary judgment; (2) no significant new and relevant evidence has come to light; and (3) the Court conducted a detailed analysis and articulated a very specific and refined construction of the limitation that will provide the finder of fact with clear guidance in resolving this question.

follows:

> Indeed, "mechanism" is defined as "1 a: a piece of machinery : a structure of working parts functioning together to produce an effect." Webster's Third New International Dictionary 1401 (1993); *see also* Mirriam-Webster Online Dictionary, *www.m-w.com* (defining "mechanism" as "1:a: a piece of machinery."). On the other hand, "member" is defined as "4: a constituent part of a whole, as . . . d(2): an essential part of a framed structure, a machine, or a device." Webster's Third New International Dictionary 1408 (1993); *see also* Mirriam-Webster Online Dictionary, *www.m-w.com*, (defining "member as "4: a part of a whole."). A mechanism, therefore, is not commonly understood to be simply a single part that has multiple components; a mechanism itself has multiple parts. Nor can "member" and "mechanism" be treated as synonymous, as Plaintiff seemingly attempts to do.

(*Id.* at 22-23.) In addition, the Court found that the specifications did not support Baran's argument that "member" and "mechanism" are synonymous.

> Indeed, as MDTech argues, the specification actually counsels that, in defining "member," the Court should err on the side of simplicity rather than on the side of complexity. The only references to "mechanism" in the specification relate to prior art, are accompanied by the term "complicated," and are the very types of elements that Baran asserts he was attempting to remedy by making his invention more simple. Given that, and absent any other source to expand the meaning of "member" as it is used in claim 7, the Court cannot define "member" as including the alternate term "mechanism."

(*Id.* at 23.) Ultimately, the Court did circumscribe the scope of its construction, however, explaining as follows:

> The Court notes, however, that, in finding that "member" does not encompass "mechanism," it only determines what "member" is <u>not</u>; it does not determine how it should be defined. For their part, the parties offer little guidance and, indeed, do

> not even attempt to define member.[15] Given that the parties do not seek to define "member," and that their sole dispute over this term is whether it could be defined to include "mechanism," the Court sees no need to further define this term. Accordingly, the Court construes "a manually operable charging member for moving the guide to the charged position against the urging of the coil spring" pursuant to Plaintiff's proposed construction, absent the term "mechanism," as follows: "a manually operable charging member that is used to create a charge or stored energy, the charging member configured to move the guide to the charged position against the urging of the coil spring."

(*Markman* Opinion at 25-26.) On summary judgment, the question is now whether the BioPince "mechanism," which undisputedly includes a "member," may, as a matter of law, infringe the "charging member limitation" of the '797 Patent, which teaches a "member configured to move the guide to the charged position against the urging of the coil spring."

b. Infringement Analysis: The BioPince Does Not Literally Infringe the Charging Member Limitation of Claim 7 of the '797 Patent

Again, " literal infringement occurs when 'every limitation recited in the claim is found in the accused device[.]'" *Bass Pro Trademarks, L.L.C. v. Cabelas, Inc.*, 485 F.3d 1364, 1369 (Fed. Cir. 2007) (quoting *Engel Indus., Inc. v. Lockformer Co.*, 96 F.3d 1398, 1405 (Fed. Cir. 1996)). Accordingly, in order to prove that the BioPince literally infringes the charging member limitation of the '797 Patent, Baran must demonstrate that the BioPince has (as the limitation was construed by the Court), "a manually operable charging member that is used to create a charge or stored

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[15] As noted at the *Markman* hearing:

> THE COURT: But, you don't even seek to define member, really, other than – what you seek to define is manually.
>
> MS. THOMPSON (counsel for MDTech): No, I seek to define member only insofar as to exclude the expansion that Plaintiffs put on it.

(Tr. at 88.)

energy, the charging member configured to move the guide to the charged position against the urging of the coil spring." (*Markman* Opinion at 59-60 (emphasis in original).)

MDTech concedes that a "mechanism" is made up of component "members." It also concedes that a "member" need not be a single component structure – it could be more than one component moving in unison, as long as the structure does not constitute a group of independent parts mechanized to work together. (*Markman* Hrg. 89.) In addition, Baran identifies the long blue or green "crank arm" as the "member" of the BioPince that reads on the charging member limitation of the '797 Patent. MDTech does not dispute that the "crank arm" is "manually operable," and is a component member of the slider-crank mechanism. Accordingly, the issue is whether the crank arm, considered independently of the remaining component members of the slider-crank mechanism, reads on the charging member limitation in the '797 Patent.

MDTech argues that the Court already determined that a mechanism is not a member, nor is it equivalent to a member. MDTech's central contention is that the BioPince's slider-crank mechanism charges the spring by virtue of the concerted action of three component members of the mechanism as a whole, not because of the action of any single component member or even the in-unison operation of multiple component members bonded together. According to MDTech, a mechanism must be treated as an entity unto itself; dividing it into its component parts (*i.e.*, "members") undermines its essential nature. Therefore, MDTech fundamentally disagrees with the proposition that the crank arm (or, for that matter, any other member of the slide-crank mechanism) could read on the charging member limitation of the '797 Patent. MDTech asserts that the theoretical distinction between a member and a mechanism is readily apparent in the difference between the way the BioPince charges the spring and the '795 Patent's teachings for charging the

spring. Whereas the '797 Patent teaches a single member working directly against the urging of the spring to compress it – without the benefit of any mechanical advantage, the BioPince uses a slider-crank mechanism consisting of a lever (the "crank arm"), which moves the "crank arm fixer," which moves the "slider link" to compress the spring with a significant mechanical advantage.[16]

For his part, Baran points out that, although the Court stated in the *Markman* Opinion that "'member' does not encompass 'mechanism,'" it did not address the converse – whether a mechanism could include a member. Further, Baran notes that the Court expressly stated that, because the parties did not ask for a definition of "member," its construction of the charging member limitation was not intended to define "member," except to conclude that it was not synonymous with "mechanism." Baran also contends that MDTech is now attempting to read into the Court's construction a limitation that the member must act "directly" against the guide, a requirement that does not appear in the Court's *Markman* Opinion. Accordingly, Baran argues that the crank arm of the BioPince satisfies the charging member limitation of the '797 Patent because it is: (1) manually operable; (2) a member; (3) used to create a charge; and (4) configured to move the guide to the charged position against the urging of the spring (albeit in conjunction with the other members of the slider-crank mechanism).

In reply, MDTech contends that Baran's argument is inconsistent with the Court's construction of "member" to exclude a "mechanism." MDTech argues that the Court's conclusion

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[16] The experts agree that there is a mechanical advantage in using the BioPince's slider-crank mechanism, and no mechanical advantage in the method of compressing the spring claimed by the '797 Patent. Dr. Rashidi testified at length regarding the scientific principles underlying the BioPince's slider-crank mechanism and the significant benefits of using that particular charging mechanism in the BioPince. The Court finds Dr. Rashidi's testimony on this point credible and unrebutted.

that "member" is not synonymous with "mechanism" would be meaningless if Baran were allowed to compare a single component of the slider-crank mechanism to the charging member in the '797 Patent for purposes of proving infringement. As stated by MDTech:

> Every manually operated mechanism necessarily includes at least one member. According to Baran's interpretation, every use of the word "member" would subsume the term "mechanism," because, in Baran's world, one cannot distinguish a mechanism from a member.

(Reply Br. at 20.) In addition, MDTech notes that the requirement that the charging member operates directly on the guide is "inherent" in the Court's construction, which requires the manually operable charging member to be "configured to move the guide." (Reply Br. at 19 (emphasis added).) MDTech notes that the crank arm – Baran's proposed "charging member" in the BioPince – is not configured to move the guide because it is separated from the guide by two other component members of the slider-crank mechanism. In other words, MDTech asserts that under no circumstances is the crank arm "configured" to move the guide because the crank arm itself is not adjacent to the guide at any point and is multiple components removed from the guide within the slider-crank mechanism.

The Court finds MDTech's arguments with respect to the charging member limitation persuasive, and, accordingly finds that MDTech is entitled to summary judgment of noninfringement. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998) (noting that summary judgment of noninfringement is required if just one limitation is not present). There is no genuine issue of material fact that the charging member limitation of claim 7 of the '797 Patent is not present in the BioPince.

First, the Court's *Markman* Opinion recognizes the fundamental distinction between a

mechanism and a member. The Court stated that a member is a "single part,"while "a mechanism itself has multiple parts." (*Markman* Opinion at 23.) The Court also specifically noted that the specifications of the '797 Patent itself distinguished members and mechanisms by referring pejoratively to prior art using "complicated biasing mechanisms," "upon which the patent sought to improve" by using a simple charging member. (*Id.* at 21.) Therefore, both Baran and the Court have previously recognized that the terms "member" and "mechanism" express fundamentally different concepts. In addition, both Baran and the Court have already concluded that Baran's stated purpose in designing his biopsy instrument was to improve on prior art by simplifying the device used to compress the spring.

By distinguishing these terms and refusing to treat them as synonymous, the Court implicitly determined that each is an entity unto itself, with independent validity.[17] Baran's argument requires the Court to dissect the slider-crank mechanism and treat each component "member" of the mechanism as functioning individually (*i.e.*, separate and apart from the other components), despite the fact that the Court discussed the definition of "mechanism" in the *Markman* Order and specifically noted that a mechanism is "a structure of working parts functioning together to produce an effect." (*Markman* Opinion at 22-23 (quoting Webster's Third New International Dictionary 1401 (1993).)

Indeed, whether a member can have multiple components is not a new issue. The Court considered the question of whether individual components of a mechanism read on a member during

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[17] An analogy may be useful in illustrating this concept. Musical notation uses notes and chords. A note is an essential component of a chord, but the chord is, nonetheless, an entity unto itself whose essential character is entirely dependent upon the combination of all of its notes. Likewise, the slider-crank mechanism in the BioPince is an entity unto itself that consists of several component members.

the *Markman* stage of this litigation. The Court described MDTech's position as follows:

> As an initial matter, the defendant does not seek to limit the term member to a single component structure. At the hearing, counsel for MDTech said: "I'm not saying it has to be a single part. I mean, if it were two things welded together that moved in unison, I would consider that still a member." (Tr. at 89.) Rather, MDTech simply argues that Plaintiff's effort to expand "member" to include the far more complicated concept of a "mechanism" reaches too broadly, and effectively rewrites the claim.

(*Markman* Opinion at 24.) In the *Markman* Opinion, the Court analyzed *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359 (Fed. Cir. 2002) in connection with this issue. (*Markman* Opinion at 21-23.) In *CCS Fitness*, the Federal Circuit held that a "member" could encompass a multi-component structure. (*Id.* at 21.) As noted in the *Markman* Opinion, the multi-component "member" in *CCS Fitness* was a single structure with multiple components. *See CCS Fitness*, 288 F.3d at 1367. *CCS Fitness* was a patent infringement lawsuit involving elliptical trainers. The "reciprocating member" in the patent at issue in that case was a straight metal beam connecting the pedals to a shaft and crank system. The accused device used a u-shaped structure having multiple components to accomplish the same motion. The components of the u-shaped structure in the accused device were connected such that they moved in unison, as opposed to in a series where the movement or action of one component causes the movement or action of the next. In construing the limitation "reciprocating member," the Federal Circuit found "that the term 'member' denotes a beam-like structure that is "a single unit in a larger whole." It is not limited to a straight-bar structure comprising a single component only." *Id.* In analyzing *CCS Fitness* for purposes of construing the "member" limitation in this case, this Court noted that the Federal Circuit "consistently referred to the beam, lever, or structure [of the patent-in-suit] in the singular, i.e., a single structure that has multiple components." (*Markman* Opinion at 22 (emphasis in original).)

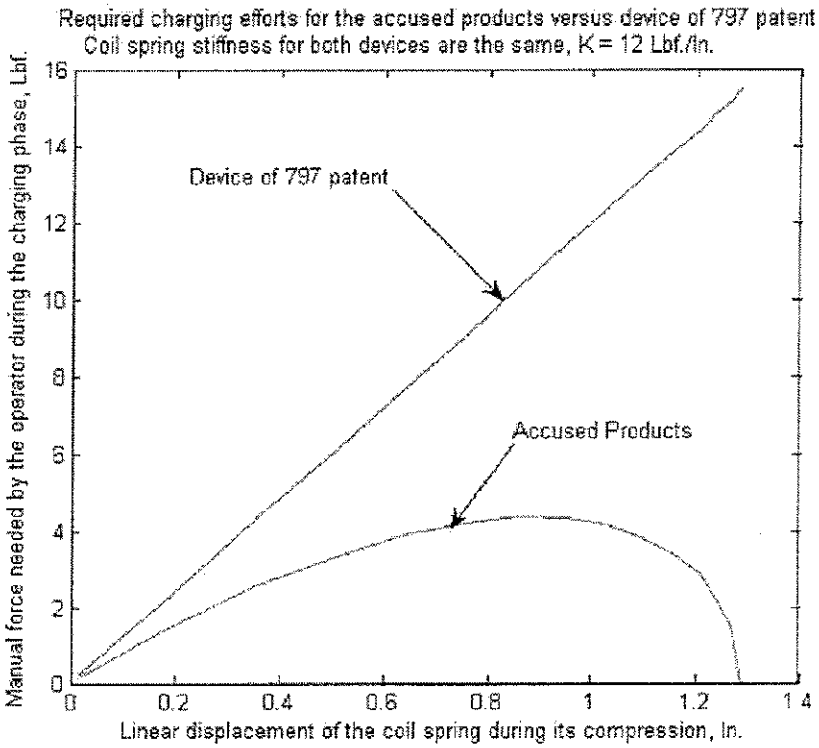
By comparison, this Court noted, "the term 'mechanism' connotes a group of independent parts working together." (*Id.* (emphasis in original).) Accordingly, this Court found that the Federal Circuit's construction of "reciprocating member" in *CCS Fitness* does not require a construction of "charging member" that treats "member" and "mechanism" as synonymous. (*Markman* Opinion at 23.)

The Court's analysis of *CCS Fitness* in the *Markman* Opinion is particularly useful now that the parties are debating the very issue the Court addressed there. The Court distinguished the "reciprocating member" in *CCS Fitness* from the ordinary meaning of "mechanism" on the grounds that the multi-component reciprocating member there was a single, unified structure that operated and moved in unison. (*Markman* Opinion at 22.) In other words, the Court concluded that the "reciprocating member" in the accused elliptical trainer was a "member" despite having multiple components because those components operated as a single, unitary piece of the elliptical trainer. Here, the components of the slider crank mechanism, including the crank arm, do not operate in unison, but in series, such that each component acts upon the next in a chain of events (leading to the compression of the spring). Accordingly, the parties' debate regarding the operation of the member in the '797 Patent and the slider-crank mechanism in the BioPince illustrates the distinction the Court explained in its *Markman* Opinion when discussing *CCS Fitness*. More importantly, the Court's analysis of *CCS Fitness* plainly supports MDTech's position – *i.e.*, that the Court's claim construction precludes a reasonable jury from finding that the crank arm is the "charging member."

Baran's comparison between the charging member in the '797 Patent and the crank arm component, *i.e.*, member, of the BioPince's slider-crank mechanism is, thus, inconsistent with the fundamental characteristics of a mechanism described in the Court's *Markman* Opinion. An

examination of the mechanical differences between the charging member in the '797 Patent and the slider-crank mechanism in the BioPince provide further support for this distinction between the two structures, moreover. (MSJ at 24.)

As Dr. Rashidi explained, there is a measurable difference between the force necessary to compress the spring, and the manner in which that force is applied in the BioPince and the patented device. (*Id.* (citing Rashidi Dep. at 185-186).) In the '797 Patent, the force necessary to compress the spring increases as the spring reaches maximum compression. (*Id.*) In contrast, the force necessary to compress the spring via the slider-crank mechanism in the BioPince is always less because the mechanism exhibits a mechanical advantage, and although the force necessary to compress the spring increases with compression to a point, by virtue of the scientific characteristics of a slider-crank mechanism, the necessary compression force then decreases to zero at full compression. (*Id.*) Dr. Rashidi's diagram at right provides a succinct graphic illustration of this comparison.



It is undisputed, moreover, that the slider-crank mechanism changes the direction of the force used to charge the BioPince, while the force used to charge the '797 device is applied in the same

direction as the compression of the spring. (*Id.* at 25.) This fact is particularly meaningful in light of the discussion above regarding *CCS Fitness*. The slider-crank mechanism can charge the spring using force applied in a direction other than the direction of the compression because the multiple components of the mechanism, acting in a series, change the direction of the force until the last component, the guide, acts against the urging of the spring in the direction of the compression. Again, this illustrates that, unlike the "reciprocating member" in *CCS Fitness*, the component parts of the BioPince's slider-crank mechanism do not act in unison. The BioPince's slider-crank mechanism is a vivid example of the type of mechanism the Court described in the *Markman* Opinion – *i.e.*, independent components working together. (*Markman* Opinion at 22.) Viewed in this light, Baran's argument that the crank arm is the charging member is necessarily inconsistent with the Court's analysis of this limitation in the *Markman* Opinion.[18]

In addition, the Court notes that Baran cannot satisfy the requirement that the member be "configured to move the guide." MDTech explains:

> There is no question that the Crank Arm is not "configured" to move the Guide; its shape or configuration would never allow it to operate on the Guide. Instead, the Crank Arm moves the Connecting Rod (30), which moves the Crank Arm Fixer (34), which moves the Slider Link (35), but it does not, and cannot move the Guide.

(Reply Br. at 19-20.) Thus, as both experts testified, the crank arm only participates in moving the guide by virtue of the concerted, sequential action of the other component members in the slider-crank mechanism, such that each component acts upon the next in a chain of events leading to the compression of the spring. Baran does not deny this reality. Baran argues though that the crank arm

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[18] While Baran is correct that this Court did not define what a member was, it most certainly defined what a member is not. The Court unequivocally concluded that a member is not a series of independent components that work together to accomplish a function by way of movements that include changes in both direction and force.

– the only "manually operable" component member of the slider-crank mechanism – is "configured to move the guide" because the guide cannot move without it – *i.e.*, unless the crank arm is manually operated, the other component parts will not engage. Thus, while Baran concedes that the crank arm never touches the guide, or directly engages it, he asserts that there is a "but for" element to its presence: but for operation of the crank arm, the guide would not move.

Baran's reasoning is inconsistent, however, with his own contention that each component member of the slider-crank mechanism can be analyzed independently for purposes of literal infringement. Baran cannot have it both ways. If the crank arm is "configured to move the guide," it is only by virtue of the concerted, sequential action of the slider-crank mechanism. Therefore, it is the action of the slider-crank mechanism as a whole that is under consideration, and Baran would have to show that a mechanism reads on a member, a showing the Court's *Markman* Opinion precludes. If, on the other hand, the slider-crank mechanism can be disarticulated into its component members for purposes of the infringement analysis, then the individual action of each component member is what is truly under consideration, not the concerted, sequential action of the mechanism as a whole. Ultimately, the claim construction implies that "configured to move the guide" presupposes that the configuration does not require multiple steps in between the operation of the member and the movement of the guide. Consequently, the crank arm – which is not, by itself, configured to move the guide – does not read on the charging member of the '797 Patent.[19]

Finally, it is worth noting that adopting Baran's argument would lead to untenable results that

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[19] The Court does not, as Baran fears, construe the concept of "configured to move the guide" to only cover the preferred embodiment of the '797 Patent. It simply concludes that a component that is several mechanical steps away from the movement of the guide, where those interim steps operate as they do within the BioPince, does not satisfy that limitation.

the Court most assuredly did not intend to countenance by its construction of the charging member limitation. In the context of the type of automated biopsy instruments at issue here, there is a logical fallacy at the heart of Baran's argument. All automated biopsy instruments include a method of charging the device so that it can be automatically discharged to collect a tissue sample. In every automated biopsy device that uses a linear spring to provide the elastic potential energy for the charge, the invention must include a means for compressing the spring, either directly or indirectly. If Baran's interpretation of the Court's claim construction is correct, then every method of compressing the spring would read on the charging member limitation of the '797 Patent. As discussed above, for example, in this case, the crank arm never comes into contact with the spring, but, because it is the "manually operable" component of the mechanism that ultimately compresses the spring, it would read on the '797's charging member limitation under Baran's interpretation of that limitation, no matter how complex the mechanism between the initial "manually operable" component and the guide, and no matter how many interim components make up that mechanism. The Court certainly did not intend to so limit the field of potential improvements to biopsy instruments in its *Markman* Opinion.[20]

Accordingly, MDTech is entitled to summary judgment of noninfringement with respect to Baran's claim that the BioPince literally infringes the charging member limitation of claim 7 of the

[20] The Court does not find, nor is it necessarily convinced, that the logical fallacy discussed above would be present in every situation in which a patentee attempts to prove infringement by arguing that a "member" reads on a "mechanism." This analysis is limited to the automated biopsy instruments at issue in this case.

'797 Patent.[21]

3. The Release Means for Retaining Limitation: "a release means for retaining the guide in the charged position"

Although summary judgment of noninfringement is required if even one limitation is not present in the accused device, *see Bai*, 160 F.3d at 1353, the Court will complete the analysis of the three disputed terms. The third disputed term of claim 7 of the '797 Patent is "a release means for retaining the guide in the charged position."

a. The Court's Construction of the Release Means for Retaining Limitation

At the *Markman* stage of these proceedings, the parties agreed that this limitation should be construed as a means-plus-function claim limitation in accordance with 35 U.S.C. § 112, ¶ 6. (*Markman* Opinion at 26.) Construction of a means-plus-function claim involves a two-step process. First, the Court must identify the recited function that the "means" performs. *Omega Eng'g, Inc.*, 334 F.3d at 1321. Next, the Court must identify the corresponding structure that performs the recited

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[21] In his Opposition Brief, Baran does not argue that the BioPince infringes the charging member limitation under the doctrine of equivalents. Accordingly, the Court need not analyze this issue. The Court will briefly address the doctrine of equivalents in the context of the charging member limitation, however, because the analysis further illustrates the reasons Baran's literal infringement arguments are unavailing.

The BioPince clearly does not infringe under either the "function, way, result" or "insubstantial differences" tests articulated above for infringement under the doctrine of equivalents. The difference between the slider-crank mechanism and the charging member claimed in the '797 Patent is apparent. Under the function-way-result test, it is undisputed that the BioPince does not perform the function at issue – *i.e.*, charging the spring – in the same <u>way</u> as the '797 Patent teaches because it uses a slider-crank mechanism that achieves a significant mechanical advantage in charging the spring. Likewise, the significant mechanical advantage the BioPince achieves by virtue of the slider-crank mechanism clearly and substantially distinguishes the BioPince from the biopsy instrument claimed in the '797 Patent under the insubstantial differences test. This is presumably why Baran did not attempt to argue that the BioPince infringes the charging member limitation under the doctrine of equivalents.

function. *Id.*

The Court conducted this analysis on the "release means for retaining the guide in the charged position" limitation in the *Markman* Opinion. With respect to the first step, the bone of contention between the parties at the *Markman* hearing was whether the function was both retaining and releasing, or just releasing. The Court discussed this issue at length and determined that the function of this element includes both retaining the guide in the charged position and releasing the guide from the charged position. The Court articulated the function as follows:

> ["a release means for retaining the guide in the charged position"] is a [m]eans-plus-function claim in which the function is "retaining the guide in the charged position and releasing, or setting free, the guide from the charged position."

(*Markman* Opinion at 50.)

In analyzing step two – the corresponding structures – the Court first described the '797 Patent's explanation of the retaining and releasing functions, with reference to Figures 4A and 8A of the '797 Patent.[22]

> As for the retaining function, the patent provides that, to convert the instrument from the discharged mode to the charged mode, "[t]he safety cap **20** and the spring guide **18** are retracted in this manner until the latching projection **102** on the release lever **22** engages in the annular external shoulder **54** of the spring guide." ('797 patent, col. 7, l. 23-27.) Fig. 4A below shows the release lever **22** and latching projection **102** as they appear in the discharged mode.

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[22] In the *Markman* Opinion, the Court discussed the corresponding structures in both the reusable embodiment and the single-use embodiment. The parties agree that the BioPince is a single-use automated biopsy instrument. Further, as the Court makes clear in the *Markman* Opinion, there is no meaningful difference between the two embodiments of the '797 Patent with respect to the retaining and releasing limitation. Therefore, for infringement purpose, the distinction between the two embodiments is not meaningful.

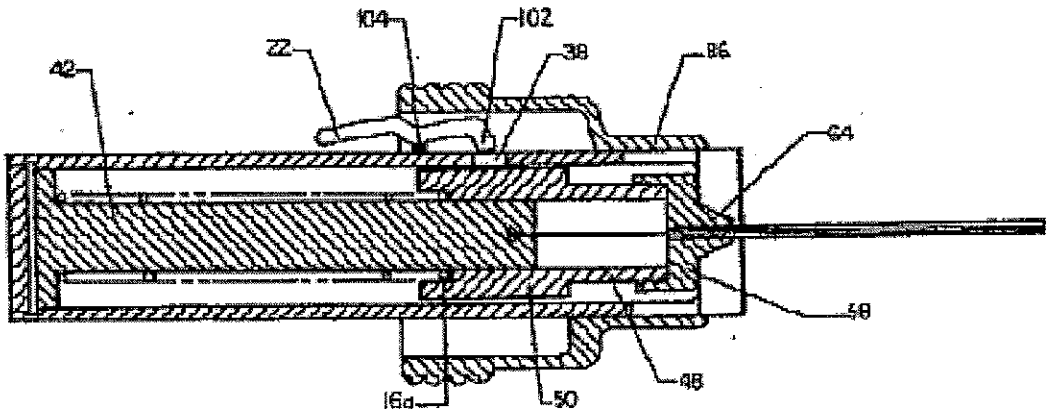
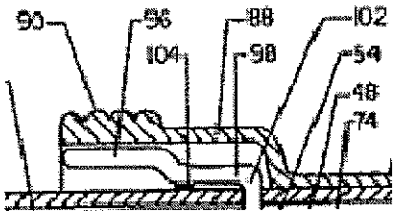


FIG. 4A

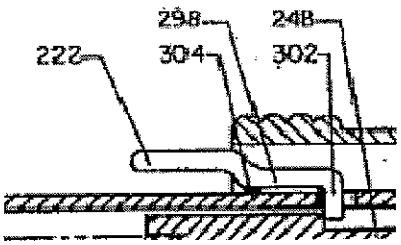
Similarly, in the single use embodiment, the patent states that conversion to the charged mode requires that "the latching projection **302** of the release lever **222** engages the external shoulder of the biopsy spring guide **218**." (*Id.*, col. 10, l. 5-7.)

As for the releasing function, the patent explains that "the operator . . . actuates the instrument by depressing the finger rest **96** of the release lever **22**, which is flexibly welded to the outer casing **12** as described hereinabove. Manipulation of the release lever raises the latching projection **102**, disengaging it from the external shoulder **54** of the spring guide **18**." ('*Id.*, col. 7, l. 61-67.) The single use embodiment is used "in precisely the same procedure" as the reusable embodiment. (*Id.*, col. 10, l. 14-16.)

In turn, as shown to the right in a portion taken from Fig. 2, "[t]he release lever **22** comprises a finger rest **96** and a mounting section **98** maintained in spaced parallel planes by a connecting web **100** . . . Mounting section **98** is formed with a latching projection **102** at one end of the release lever and is flexibly secured to the outer casing with a spot weld **104**." (*Id.*, col. 6, l. 25-32).



Likewise, the single use embodiment contains substantially similar features (with different corresponding numbers), as shown to the right in a portion of the illustration taken from Fig. 8. The description provides that "[t]he mounting section **298** of the release lever **222** is flexibly welded to the



outer casing at **304**. (*Id.*, col. 9, l. 36-37.)

(*Markman* Opinion at 31-33.) The Court then described the structures corresponding to the retaining and releasing function as follows:

> Based on the specification described above, the Court finds that the structures corresponding to the recited functions in this mean-plus-function limitation are the following: . . . for the single use embodiment (Figs. 5-8A), the release lever **222**, including the latching projection **302**, the finger rest (not marked by a reference numeral), and the mounting section **298**, as well as the equivalents thereof.

(*Id.* at 33.) The Court noted that "[a]ll of these structures and their elements are specifically linked to the stated functions of retaining and releasing the spring guide, either in the description of the operation of the instrument or the detailed description of the structures themselves." (*Id.*)

b. Infringement Analysis

MDTech contends that summary judgment of noninfringement is appropriate because, as a matter of law, the BioPince does not infringe the retaining and releasing means-plus-function limitation of the '797 Patent. There is, however, a threshold issue raised by MDTech that must be addressed at the outset.

i. Whether It Is Appropriate to Analyze Baran's Theory of Infringement Even Though the BioPince Is Not Intended to Be Operated Using the Alternative Method He Proposes

According to MDTech, there is only one legitimate way to "fire" or release the BioPince when it is charged and ready: by pressing the firing button on the end of the plastic casing farthest from the distal end of the needle. Baran disagrees, and his claim that the BioPince infringes the retaining and releasing limitation of the '797 Patent depends entirely on an alternative method of firing/releasing the charged BioPince.

Specifically, Baran asserts that physicians using the BioPince can, and do, release it from the charged position by pulling up on the crank arm to disengage the latching projection from the shoulder in the opening of the crank arm. This procedure is described in greater detail in Dr. Haaga's expert report (with reference to Figures 12 and 13 of Dr. Haaga's expert report):

> As illustrated below in Figures 12 and 13, the BioPince products include a strut or lever stage 60 provided with a release lever 65 that includes a latching projection 70 and a mounting section 75. Applying the claim construction provided by the Court, the latching projection 70 of the release lever 65 is releasably engaged to a shoulder 80 in an opening 85 in the charging member 55, such that: i) when the latching projection 70 engages the shoulder 80 of the charging member 55, the guide 40 is retained in its charged position and ii) when the latching projection 70 is disengaged from the shoulder 80 in the opening 85 of the charging member 55 (e.g., by lifting up on the charging member 55 at the site where the strut 60 pivotally connects to the charging member 55), the guide 40 is released or set free from its charged position. Based at least on the foregoing, it is my opinion that this structure (i.e., the release lever 65 that includes a latching projection 70 and a mounting section 75) represents an equivalent structure of the corresponding structures set forth in the Court's claim construction. Accordingly, it is my opinion that the BioPince products satisfy [the releasing and retaining] limitation.

(Haaga Expert Report ¶ 50, Doc. 174-1.) Figures 12 and 13 from Dr. Haaga's Expert Report are reproduced below.[23]

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[23] The captions to figures 12 and 13 do not appear in Dr. Haaga's report. With one notable exception, the Court has used captions that conform to the numbering in Dr. Haaga's report and the names used throughout this opinion. The exception is the release "lever" 65 in Figure 12. The parties debate whether 65 is a lever or a cantilever. "Release lever" is Haaga's moniker.

Figures 12 & 13 from Dr. Haaga's Expert Report:

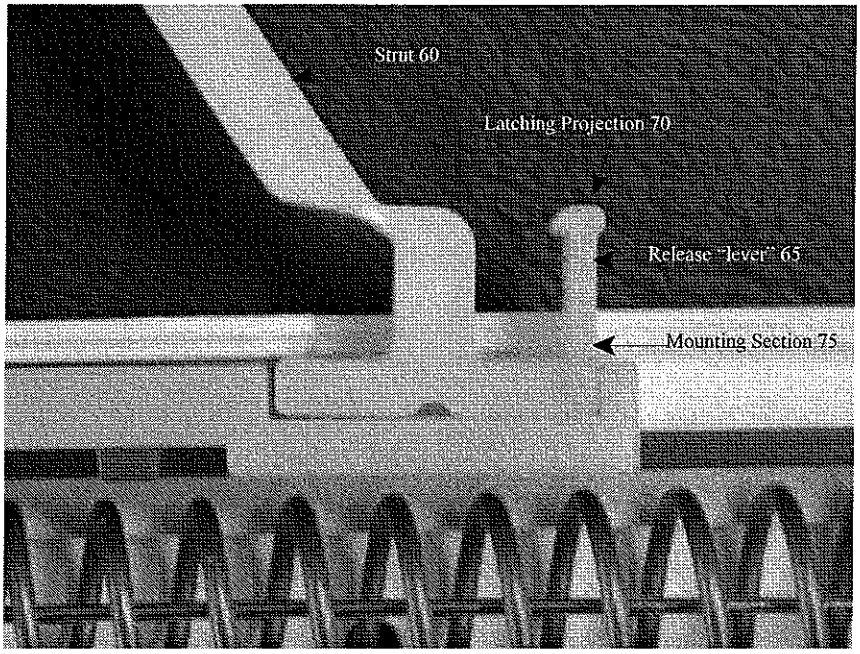

Figure 12 – Haaga's Expert Report (captions added)

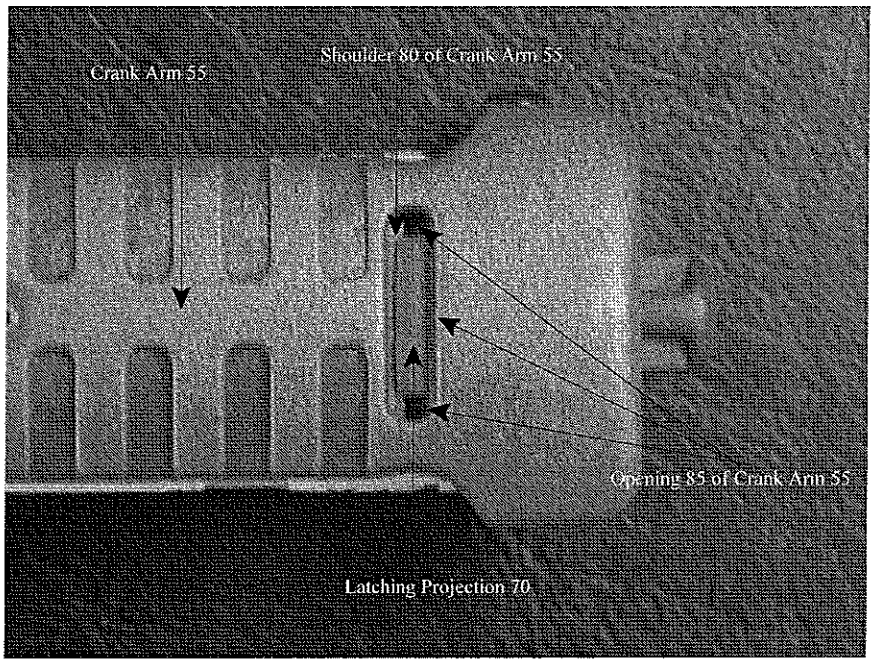

Figure 13 – Haaga's Expert Report (captions added)

MDTech's first argument with respect to the retaining and releasing limitation is that Baran has not even attempted to argue that the BioPince infringes because all of his arguments relate to an improper, unknown, and dangerous method of discharging the BioPince, *i.e.*, the crank arm discharge method described by Dr. Haaga above.[24] Indeed, Baran does not contend that discharging the BioPince in the manner described in the instructions that accompany the commercially available BioPince – *i.e.*, by pressing the firing button on the end of the plastic casing farthest from the distal end of the needle infringes the releasing and retaining limitation, either literally or under the doctrine of equivalents. Accordingly, the threshold issue is whether a device may infringe a means-plus-function limitation of a patent when the structures of the device which correspond to the function at issue are not intended to perform that function.

MDTech cites *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1555-56 (Fed. Cir. 1995), for the principle that "a device does not infringe simply because it is possible to alter it in a way that would satisfy all the limitations of a patent claim." MDTech

[24] Dr. Haaga's method will be described as the "crank arm discharge" method in this Memorandum and Order.

contends that the Court should evaluate five factors[25] listed in *High Tech* to determine whether an altered device infringes. MDTech argues that the BioPince does not infringe because there is no evidence that (1) it "intended or anticipated" physicians to use the crank arm to discharge the BioPince; (2) physicians actually operate the BioPince this way; (3) promotional materials or instructions teach or reference this method; or (4) this method serves a functional purpose not already accomplished. Further, MDTech cites *Cross Medical Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311 (Fed. Cir. 2005) for the proposition that the five-factor *High Tech* test applies "where a claimed limitation is not present until the device is used in an infringing manner – even if the device need not be physically altered in order to infringe." (MSJ at 17.)

Baran relegates MDTech's *High Tech* argument to a footnote, dismissing it as inapposite because the crank arm discharge method is merely one way of using the BioPince as designed. In other words, Baran distinguishes this case from *High Tech* because the crank arm discharge method does not involve an alteration or modification of the BioPince. Baran does not cite any cases or other authority in support of his position.

There is truth in both parties' arguments. The rule in *High Tech* (*i.e.*, that altering a device

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[25] As stated by MDTech, the five factors in *High Tech* are:

(1) whether the accused infringer "intended or anticipated" that consumers would modify the accused device to operate in an infringing manner;
(2) whether consumers "actually operated" the device in an infringing manner;
(3) whether the device was "designed to be altered or assembled" before operation;
(4) whether the accused infringer's promotional materials refer to an infringing use; and
(5) whether the device "would serve any functional purpose" in its modified configuration "not already accomplished" by other configurations.

(MSJ at 15-16 (citing *High Tech*, 49 F.3d at 1555-56).)

so that it is infringing is not sufficient to prove infringement) is well-established. *See Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358, 1369 (Fed. Cir. 2009) ("Revolution points out that a device does not infringe simply because it is possible to alter it in a way that would satisfy all the limitations of a patent claim. . . . This statement is certainly correct.") (omitting citations and quotations). The factual distinction Baran identifies is also valid and important, however. *See id.* at 1370. The crank arm discharge method does not involve a physical alteration of the BioPince, it is merely an alternative way of using the identical device to perform the releasing function, albeit not a recommended one.

The distinction Baran raises between this case and *High Tech* implicates fundamental principles of patent protection. A patent provides the owner with the right to exclude others from "making, using, offering for sale, or selling" the patented invention. 35 U.S.C. § 154(a)(1); 35 U.S.C. § 271(a). "Making" an invention refers to combining all of its parts into an operable whole. *See Deep South Packing Co. v. Laitram Corp.*, 406 U.S. 518, 528 (1972). The owner of an apparatus patent has the right to exclude others from making the same apparatus. The Federal Circuit has articulated the general rule as follows: "in determining whether a product claim is infringed, we have held that an accused device may be found to infringe if it is reasonably capable of satisfying the claim limitations, even though it may also be capable of non-infringing modes of operation." *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1343 (Fed. Cir. 2001) (citing *See Intel Corp. v. United States Int'l Trade Comm'n*, 946 F.2d 821, 832 (Fed.Cir.1991); *Key Pharms., Inc. v. Hercon Labs. Corp.*, 981 F.Supp. 299, 310 (D.Del.1997), *aff'd*, 161 F.3d 709 (Fed.Cir.1998); *Huck Mfg. Co. v. Textron, Inc.*, 187 USPQ 388, 408 (E.D.Mich.1975) ("The fact that a device may be used in a manner so as not to infringe the patent is not a defense to a claim of infringement against a

manufacturer of the device if it is also reasonably capable of a use that infringes the patent.").

Intel, 946 F.2d 821, cited by *Hilgraeve*, is the case most frequently cited for this general rule. In *Intel*, the patent at issue was for an erasable programmable read-only memory apparatus. *Id.* One of the claim limitations was a "programmable selection means" for choosing between two modes of operation. Although the devices were marketed and sold to operate in only the non-infringing mode of operation, they could be operated in either mode as designed and sold. The Federal Circuit found infringement, stating that "the accused device, to be infringing, need only be capable of operating in the [infringing] mode." *Id.* at 832. Evidence of actual use in the infringing mode, moreover, was not required, *id.*, because "making" an infringing apparatus means unifying all of its parts into an operable whole that infringes the patent at issue. How that apparatus is used is a separate question that implicates the other rights conferred by §154(a)(1).

The rule in *High Tech* is a corollary to this basic principle. That is, if an accused device must be altered to be considered the "same" product, then it was not infringing as made. In fact, the Federal Circuit in *Hilgraeve* "*cf.*"[26] cited *High Tech*, 49 F.3d at 1556 for the general rule, noting in a parenthetical that "an accused device does not infringe if it does not infringe in its normal configuration, even if it may be altered into an infringing configuration under unusual

[26] The Bluebook defines "*cf.*" as follows: "Cited authority supports a proposition different from the main proposition, but sufficiently analogous to lend support."

circumstances." *Hilgraeve*, 265 F.3d at 1343; *Intel*, 946 F.2d at 832.[27] Therefore, the five-

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[27] There is a line of Federal Circuit authority, including recent cases, that, at first blush, appears to contradict *Intel* and *Hilgraeve* by holding that "[i]n order to prove direct infringement, a patentee must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit." *ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007) (citing *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1275-76 (Fed. Cir. 2004)). In *ACCO*, the Federal Circuit stated:

> Here, the parties do not dispute that the accused device can be operated in either of two modes-the infringing Dornfeld method or the noninfringing press-to-lock method. Because the accused device can be used at any given time in a noninfringing manner, the accused device does not necessarily infringe the . . . patent.

Id. Although the facts in *ACCO* appear analogous to the scenario at bar, in which there are two distinct methods of operating the BioPince at issue, the claim at issue in *ACCO* was induced infringement as opposed to infringement by a manufacturer. In fact, the Federal Circuit expressly rejected the defendant's argument under *Hilgraeve*:

> We are further unpersuaded by ACCO's reliance on *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336 (Fed.Cir.2001), which states that an accused device may be found to infringe a product claim "if it is reasonably capable of satisfying the claim limitations, even though it may also be capable of non-infringing modes of operation." *Id.* at 1343. That broad legal statement does not alter the requirement that ACCO must prove specific instances of direct infringement or that the accused device necessarily infringes the patent in suit, in order to sustain the jury verdict of induced infringement. Hypothetical instances of direct infringement are insufficient to establish vicarious liability or indirect infringement.

ACCO, 501 F.3d at 1313. Although the distinction is only implicit in *ACCO*, in that case, direct infringement arose as an element of induced infringement by a non-manufacturer, not infringement by a manufacturer. The Federal Circuit recently applied the same standard for the direct infringement element in an induced infringement case. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009) (citing *ACCO*, 501 F.3d at 1313). The basis of the distinction between manufacturers and non-manufacturers is well-articulated in *Huck Mfg. Co.*, 187 U.S.P.Q. at 408:

> The fact that a device may be used in a manner so as not to infringe the patent is not a defense to a claim of infringement against a manufacturer of the device if it is also reasonably capable of a use that infringes the patent. In this respect a distinction is drawn between an alleged manufacturing infringer on the one hand and an alleged using infringer on the other hand. For a person who uses a device,

factor analysis described in *High Tech* is applicable to identify an exception to, or extension of, the general rule; *i.e.*, where the potential alteration or modification was effectively a means of evading the patent rights of another, an accused product may still infringe. Accordingly, because the crank arm method of discharging the BioPince does not involve a physical alteration or modification, *High Tech* is not the applicable authority. *See Revolution Eyewear*, 563 F.3d at1370 (distinguishing *High Tech* on the grounds that the accused device in that case had to be altered to infringe).

The question, therefore, is whether the BioPince, as designed and sold, is reasonably capable of a use that infringes the patent. *Hilgraeve*, 265 F.3d at 1343. The Federal Circuit very recently

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> infringement is determined by the use to which the invention is actually put, but for a manufacturer, infringement is determined by the use to which the device may reasonably be put or of which it is reasonably capable.

Thus, the Federal Circuit applies the rule stated in *Intel* and *Hilgraeve* – that "an accused device may be found to infringe if it is reasonably capable of satisfying the claim limitations, even though it may also be capable of non-infringing modes of operation" – in cases in which the plaintiff asserts a direct infringement claim against the manufacturer of the accused product; the rule stated in *ACCO* – that the accused device does not necessarily infringe if it can be used in a noninfringing manner at any given time – applies in cases in which the plaintiff asserts an induced infringement claim against a non-manufacturer of the accused product. Because this case falls into the former category, the rule stated in *Intel* and *Hilgraeve* applies.

Furthermore, the Federal Circuit has distinguished between cases involving a structural limitation in an apparatus claim and a means limitation in an apparatus claim. For example, in *Cross Medical*, 424 F.3d at 1311-12, the Federal Circuit analyzed a spinal fixation implant apparatus that included a structural claim requiring the anchor of the device to be in contact with bone. *Id.* Although MDTech cites *Cross Medical* for the proposition that the *High Tech* analysis applies even in the absence of physical alteration of the apparatus, *Cross Medical* did not involve a means-plus-function claim. 424 F.3d at 1311. In contrast, in *Fantasy Sports Properties, Inc. v. Sportsline.com, Inc.*, 287 F.3d 1108, 1117-18 (Fed. Cir. 1998), the Federal Circuit held that a means-plus-function claim was infringed because the apparatus was capable of infringing, regardless of whether it was configured to be used in an infringing manner. *See also R.A.C.C. v. Stun-Tech, Inc.*, 49 U.S.P.Q. 2d 1793 (Fed. Cir. 1998) (unpublished). This case is more analogous to *Fantasy Sports* than *Cross Medical* because the releasing and retaining limitation is a means-plus-function limitation.

addressed a similar issue in *Revolution Eyewear*, 563 F.3d 1358. In *Revolution Eyewear*, the accused device was "a spectacle frame that supports an auxiliary frame, enabling the user to securely fasten a second set of lenses (e.g., sunglass lenses) onto the primary frame (often holding prescription lenses)." *Id.* at 1362. One of the claims of the patent at issue relating to the primary frames was "said first magnetic members capable of engaging second magnetic members of an auxiliary spectacle frame." *Id.* at 1369. The Defendant did not dispute that its primary frames included all of the limitations of the claim, but argued that neither its auxiliary frames nor any commercially available auxiliary frames could be used in conjunction with its primary frames in an infringing manner, *i.e.*, by "top-mounting." *Id.* The Plaintiff, however, presented auxiliary frames capable of such use that had been constructed specifically for purposes of the litigation to prove that the accused device was theoretically capable of being used in an infringing manner. *Id.* The Federal Circuit found infringement, reasoning that the case before it was analogous to *Intel Corp.*, and distinguishable from *High Tech.*, because, *inter alia*, it does not involve an alteration of the product as designed or sold.

> Just like the accused product in *Intel*, Revolution's primary frames, although not specifically designed or sold to be used with top-mounting auxiliary frames, are nevertheless capable of being used in that way-the three specially made auxiliary frames proved so. It is irrelevant that Revolution's auxiliary frames, or any other commercially available auxiliary frames, are not actually used in a top-mounting configuration or cannot be so used.

Id. at 1370.

The Court finds that this case is analogous to *Revolution Eyewear* and, accordingly, concludes that summary judgment of noninfringement would not be appropriate if Baran's asserted crank arm discharge method reads on the releasing and retaining limitation of the '797 Patent. The

crank arm discharge method does not require physical alteration of the BioPince; it is an alternative method of using the device. Therefore, whether physicians or users of the BioPince actually employ the crank arm discharge method is irrelevant. Indeed, in *Revolution Eyewear*, the plaintiff did not even attempt to demonstrate that anyone actually practiced the infringing use – the plaintiff specially constructed auxiliary frames capable of infringing, and the Court accepted these litigation-specific models as dispositive proof on the issue. 563 F.3d at 1370. Accordingly, if the crank arm discharge method satisfies the limitations of the '797 Patent, then the BioPince is reasonably capable of an infringing use.[28]

ii. Infringement Analysis of Baran's Crank Arm Discharge Method

MDTech argues that, even if the BioPince is capable of being operated using Baran's crank arm discharge method, that method does not satisfy the releasing and retaining limitation of the '797 Patent.

a. Standard for Statutory Equivalents – § 112 ¶ 6

The retaining and releasing limitation is a means-plus-function limitation under 35 U.S.C. 112 ¶ 6. "When a patentee chooses to claim a 'means' for performing a specified function, the means clause covers only 'the corresponding structure, material, or acts described in the specification and equivalents thereof.'" *Applied Medical Resources Corp. v. United States Surgical Corp.*, 448 F.3d 1324, 1338 (Fed. Cir. 2006) (Dyk, J., dissenting). The test for infringement of a means-plus-

[28] Other issues distinguishing this case from *Revolution Eyewear* are best addressed in the context of the infringement analysis. For example: MDTech asserts that the crank arm discharge method does not satisfy the releasing and retaining limitation because there is no connection between the patent claims and the new method; Baran asserts that MDTech is attempting to add a limitation not present in the patent – *i.e.*, a release means appropriate for performing a biopsy.

function claim limitation is as follows:

> Literal infringement of a § 112, ¶ 6 limitation requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification. . . . Functional identity and either structural identity or equivalence are both necessary.

Odetics, Inc. v. Storage Tech. Corp., 185 F.3d 1259, 1266 (Fed. Cir. 1999) (omitting citations). Proving infringement of a means-plus-function limitation thus involves three steps. The first step is to identify the relevant structure in the accused device. *See Applied Medical*, 448 F.3d at 1333. The second step is to prove that that structure performs the identical function as the corresponding structure in the specifications of the patent at issue. The third step is to prove that the corresponding structures perform that function in substantially the same way with substantially the same result. *Id.* (citing *Kemco Sales, Inc. v. Control Papers, Co.*, 208 F.3d 1352, 1364 (Fed. Cir. 2000)).[29]

This statutory equivalents test under § 112 ¶ 6 is not the same as the doctrine of equivalents, although the two are closely related. Because the function of the relevant structure in the accused device and the corresponding structure in the specification must be identical, the statutory equivalents test reduces the doctrine of equivalents' function, way, result test to the latter two prongs – the "way" and "result." *See Odetics*, 185 F.3d at 1267. Statutory equivalents exist "if the assertedly equivalent structure performs the claimed function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification." *Id.* The Federal Circuit explained the difference between statutory equivalence and the doctrine of equivalents in *Odetics*:

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[29] Although the parties debate whether MDTech's analysis impermissibly employs a component-by-component approach to structural equivalence, they agree that the standard articulated here is the proper standard for § 112 ¶ 6 equivalence.

> [T]he statutory equivalence analysis, while rooted in similar concepts of insubstantial differences as its doctrine of equivalents counterpart, is narrower. . . . This is because, under § 112, ¶ 6 equivalence, functional identity is required; thus the equivalence (indeed, identity) of the "function" of the assertedly substitute structure, material, or acts must be first established in order to reach the statutory equivalence analysis. . . . The content of the test for insubstantial differences under § 112, ¶ 6 thus reduces to "way" and "result." That is, the statutory equivalence analysis requires a determination of whether the "way" the assertedly substitute structure performs the claimed function, and the "result" of that performance, is substantially different from the "way" the claimed function is performed by the "corresponding structure, acts, or materials described in the specification," or its "result." Structural equivalence under § 112, ¶ 6 is met only if the differences are insubstantial . . . .

185 F.3d 1267 (omitting citations).

Further, the statutory equivalents analysis is not a component-by-component comparison of structure and function. *Id.* at 1268. Instead, the relevant overall structure is that which corresponds with the overall function. *Id.* As stated in *Odetics*, a means-plus-function limitation

> is literally met by structure, materials, or acts in the accused device that perform the claimed function in substantially the same way to achieve substantially the same result. The individual components, if any, of an overall structure that corresponds to the claimed function are not claim limitations. Rather, the claim limitation is the overall structure corresponding to the claimed function. This is why structures with different numbers of parts may still be equivalent under § 112, ¶ 6, thereby meeting the claim limitation.

Id. As discussed below, the parties debate whether MDTech has violated the rule against component-by-component analysis.

b. The Relevant Structure

Baran asserts that the structure for the release means for retaining limitation in the BioPince consists of (referring to Figures 12 and 13 above) the crank arm **55**, with the opening in the crank arm **85**, and the shoulder within the opening 80; as well as the release "lever" **65**, with the latching projection **70** and the mounting section **75.** According to Baran, this crank arm releasing and

retaining structure is the structure of the BioPince that corresponds with the releasing and retaining limitation of the '797 Patent.

c. Whether the Crank Arm Releasing and Retaining Structure Identified by Baran Performs the Identical Function as the Disclosed Releasing and Retaining Structure

The Court construed the functions of the "release means for retaining the guide in the charged position" limitation as "retaining the guide in the charged position and releasing, or setting free, the guide from the charged position." (*Markman* Opinion at 30-31.) MDTech argues that the crank arm structure identified by Baran for releasing and retaining the guide does not perform the same functions because (1) it would be reckless to perform a biopsy by releasing the charge in that manner and (2) pulling up on the crank arm does not release the guide, and, therefore, the slot in the crank arm was not retaining the guide either. Both of MDTech's arguments fail.

First, Baran correctly notes that the "release means for retaining the guide in the charged position" limitation, as construed by the Court, does not require a release that is suitable for performing a biopsy. Adding this requirement would impermissibly add an unclaimed limitation. *Applied Medical*, 448 F.3d at 1339 (Dyk, J., dissenting) ("a court may not import unclaimed functions into a means-plus-function limitation"). Therefore, although it is undisputed that Baran's crank arm structure for releasing and retaining the guide cannot perform the release function in a manner suitable for a biopsy, this is irrelevant. *Id.* Second, pulling up on the crank arm does release the guide from the charged position, as was clear from the experts' demonstrations depicted in their video depositions. (MSJ, Exs. E, F.) It does not release the guide from the slider-crank mechanism, but, again, that is not required by the Court's construction of this limitation. Further, the slot in the

crank arm does retain the guide in the charged position, at least to the extent that the guide cannot remain in the charged position unless the latching projection is engaged in the slot. (*Id.*)

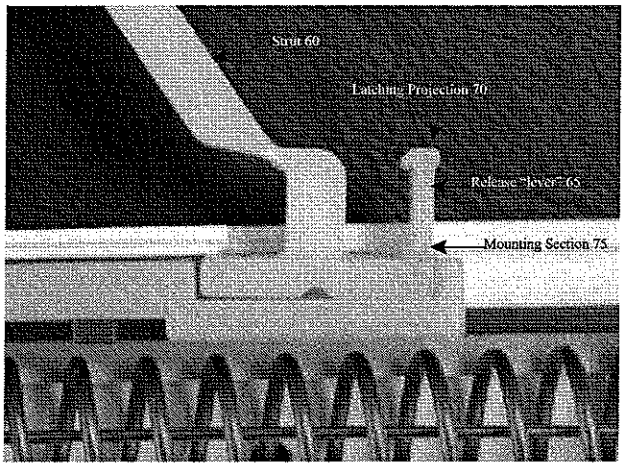
Accordingly, the Court finds that the structure identified by Baran performs the identical functions disclosed in the '797 Patent for the releasing and retaining limitation. That is, "retaining the guide in the charged position and releasing, or setting free, the guide from the charged position." (*Markman* Opinion at 30-31.)

d. Structural Equivalence: the "way" and the "result"

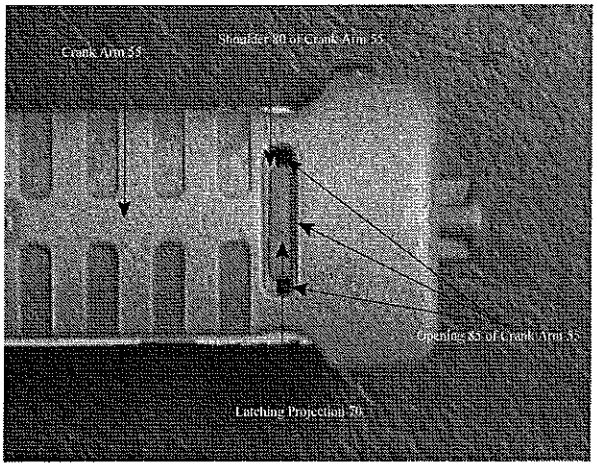
Having found that the structure identified by Baran in the BioPince performs the retaining and releasing functions disclosed in the '797 Patent, the final step of the analysis is to determine whether that structure performs the "function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification." *Odetics*, 185 F.3d at 1267 (citing 35 U.S.C. § 112 ¶ 6). It is on this stage that Baran falls off the tight-rope.

The structures Baran identifies as performing the releasing and retaining functions consists of (referring to Figures 12 and 13, reproduced below) the crank arm **55**, with the opening in the crank arm **85**, and the shoulder within the opening **80**; as well as the release "lever" **65**, with the latching

projection **70** and the mounting section **75.**

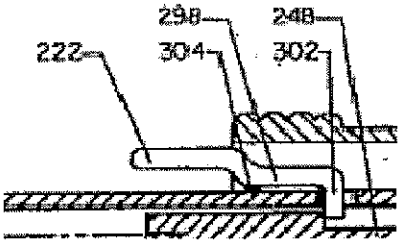


(Figure 12)



(Figure 13)

In the *Markman* Opinion, the Court identified the corresponding structures in the '797 Patent as "the release lever **222**, including latching projection **302**, the finger rest (not marked by a reference numeral), and the mounting section **298**, as well as the equivalents thereof." (*Markman* Opinion at 33 (depicting Figure 5-8A of the '797 Patent, which is reproduced at right).)

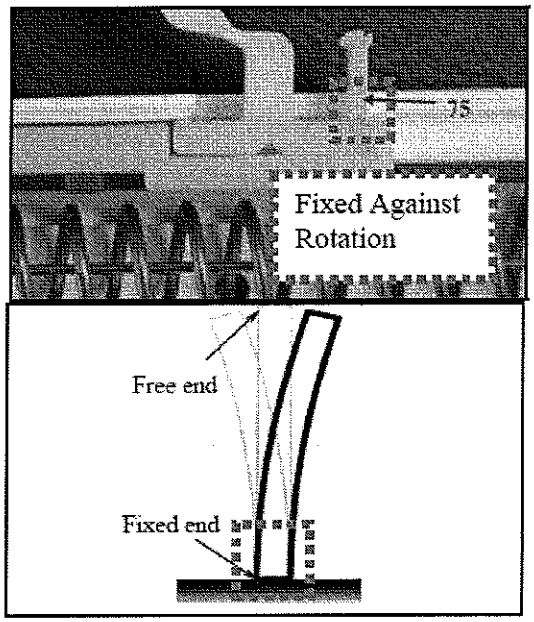


In order to prove infringement, Baran must show that the structures he identifies in the BioPince, "perform[s] [the releasing and retaining] function[s] in substantially the same way with substantially the same result" as the corresponding structures in the '797 Patent (keeping in mind the rule against a component-by-component analysis). *See Odetics*, 185 F.3d at 1267 (emphasis added).

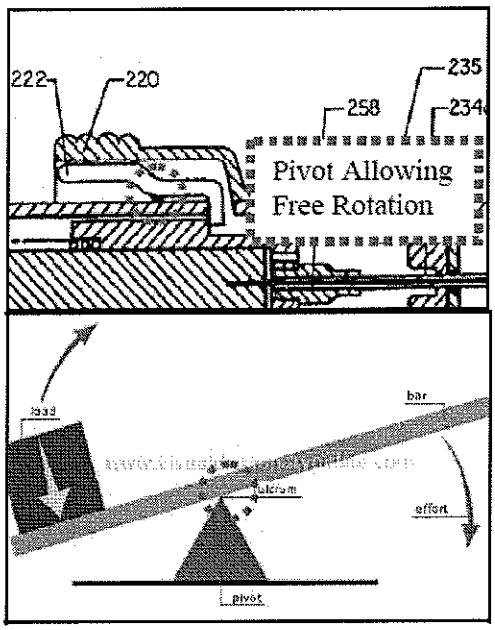
The Corresponding Structures Do Not Perform the Function in Substantially the Same Way

MDTech argues that the overall structures disclosed in the '797 Patent and identified by Baran in the BioPince for the releasing and retaining functions perform those functions in substantially different ways. First, MDTech contends that the structure at the heart of Baran's crank arm method for releasing the BioPince is a cantilever, while the corresponding structure central to the releasing function disclosed in the '797 Patent is the release lever **222**. MDTech argues that the physical and scientific characteristics of a cantilever and a lever are definitively established and scientifically distinct. As explained by Dr. Rashidi, levers pivot around a fulcrum; cantilevers flex when force is applied to their free end. (Reply at 12.) MDTech further notes that this distinction is quantifiable in terms of the force necessary to move the latching projection of the BioPince and the release lever element of the '797 Patent. MDTech illustrates its comparison of a cantilever and a lever as follows:

The BioPince Cantilever



The '797 Patent's Lever



(Reply at 13.) MDTech argues, moreover, that the way in which the releasing is performed magnifies the physical distinctions between the structures in the BioPince and the corresponding structures disclosed in the '797 Patent. Whereas the user must pry up on the crank arm of the BioPince to release it from the cantilever latching projection, the '797 Patent teaches releasing the guide by pressing down on the finger rest of the release lever **222** to raise the latching projection **302** on the other end of the release lever.

Baran argues that MDTech's analysis is an improper component-by-component approach focused on just one component of the relevant structure – the release lever. In addition, Baran argues that the flexing of the cantilever in the BioPince is substantially equivalent to the flexing of the release lever in the claimed invention. Baran contends that the way in which the corresponding structures in the BioPince and the claimed invention perform the releasing function is substantially the same because both the crank arm and the release lever "move upwards" to free the guide. (Opp'n Br. at 25.)

While the Court is cognizant of the need to avoid a component-by-component analysis, MDTech correctly notes that it is not improper to give special attention to a particularly important component of the relevant corresponding structures. *See Solomon Techs., Inc. v. Int'l Trade Comm'n*, 524 F.3d 1310, 1317 (Fed. Cir. 2008) (allowing "for greater weight to be given to individual components that play a central role in the identified structure"). The Court finds that the cantilever/latching protrusion in the BioPince and release lever in the claimed invention are such structures with respect to the releasing function. These structures play an essential role in releasing the charge in the BioPince and the claimed invention.

The Court is also persuaded by MDTech's argument that no reasonable juror could find that

the corresponding structures – one of which is primarily characterized by a cantilever and the other a lever – perform the function in substantially the same manner. First, the differences between a cantilever and a lever are elementary scientific principles beyond legitimate dispute. (*See* Rashidi Dep. at 248-49.) As Rashidi explained in some detail at his deposition, a lever employs a fulcrum and multiplies effort, while a cantilever is a beam that is anchored at one end and flexes at the other. (*Id.*) Just as a see-saw and a diving board do not function in substantially the same ways in lifting a child to exciting heights, a lever and a cantilever do not release the guide in substantially the same way. Among other things, a lever pivots on a fulcrum while a cantilever flexes. Therefore, Baran's argument that the "flexing" of the release lever and the cantilever/latching protrusion is substantially equivalent is nonsensical. Although Baran attempts to minimize this distinction by referring to a cantilever as a "flexible lever," the Court is persuaded by comparisons of the scientific principles at work, not semantics. Baran's expert, Haaga, moreover, completely failed to articulate a plausible explanation at his deposition of how the structures associated with the crank arm release method and corresponding structures in the claimed invention perform the releasing function in substantially the same way. (Haaga Dep. at 194-198, 217-218.)

Baran attempts to overcome the clear and manifest difference between a lever and a cantilever by defining the "way" in which the structure performs the function very generally – *i.e.*, as "upward motion" to release the guide. This is clever (especially within the context of a relatively complex multi-step analysis); however, it improperly conflates two parts of the § 112 ¶ 6 analysis. Namely, Baran's articulation of the "way" of performing the releasing function adds virtually nothing to the function itself. The way in which the releasing function is performed by the corresponding structures involves far more than an "upward motion." Although the Court has found (above) that

the "identical function" requirement is satisfied here, it will not permit Baran to bootstrap the remaining requirements to that finding. Accordingly, Baran cannot satisfy the test for statutory equivalents because the way in which the BioPince and the claimed invention perform the releasing function are not substantially equivalent.

The Actions of the Corresponding Structures Do Not Lead to Substantially the Same Result

Baran uses the same over-generalization tactic to argue that the result of the release of the BioPince and the claimed invention is substantially the same. In fact, Baran expressly states that "the result is simply the release of the guide." (Opp'n Br. at 26.) In support of this broad characterization of the result, Baran contends that whether the release is one which could actually be used to perform a biopsy is irrelevant because "[t]he claim is directed to a biopsy instrument, not a method for performing a biopsy." (*Id.*) Consequently, Baran argues that it is irrelevant that, compared to the release method taught by the claimed invention, the crank arm method for releasing the BioPince produces a release that (1) is not suitable for taking a biopsy; (2) is clearly more violent and erratic; and (3) leaves the device in a half-cocked position.

It is true that claim 7 of the '797 Patent does not claim a method for performing a biopsy. This statement properly focuses the analysis on the claims of the patent at issue. That same focus reveals the flaw in Baran's argument, however. The claims of the '797 Patent do not teach a slow-release, erratic means of dry-firing the claimed invention. The means-plus-function limitation, as construed by the Court, recites the following function: "retaining the guide in the charged position and releasing, or setting free, the guide from the charged position." To say that, for purposes of the statutory equivalents analysis, the result is that the guide is retained and then released deprives the result prong of any meaningful role in the analysis. Therefore, the purpose of the invention and its

specifications must inform the analysis of whether the result is substantially the same. The '797 Patent claims an automated biopsy instrument. Whether the structures for performing the releasing function are capable of a release appropriate for taking a biopsy must be relevant to the analysis of whether the result is substantially the same. Applying this principle here, because it is undisputed that the crank arm release method is not appropriate for taking a biopsy, the result is not substantially the same unless the purpose of the claimed invention is irrelevant. Accordingly, the last requirement of statutory equivalence is not satisfied as a matter of law and MDTech is entitled to summary judgment of noninfringement.

III. CONCLUSION

In summary, MDTech is entitled to summary judgment of noninfringement because there is no genuine issue of fact sufficient permit a reasonable jury to conclude that either of the following limitations of claim 7 of the '797 Patent is infringed:

(1) "a manually operable charging member for moving the guide to the charged position against the urging of the coil spring" and,

(2) "a release means for retaining the guide in the charged position."

For the foregoing reasons, Baran's *Motion for Leave to File Sur-Reply* (Doc. 181) is **DENIED**, MDTech's *Motion for Summary Judgment of Noninfringement* (Doc. 164) is **GRANTED** and this case is **DISMISSED**.

IT IS SO ORDERED.

s/Kathleen M. O'Malley
KATHLEEN McDONALD O'MALLEY
UNITED STATES DISTRICT JUDGE

Dated: September 30, 2009